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DEPARTMENT OF VETERANS AFFAIRS
Washington DC 20420

June 12, 2020

In Reply Refer To: 001B
FOIA Request: 20-07181-F

Via Email

This is the Initial Agency Decision to your June 6, 2020 Freedom of Information Act (FOIA) request to the U.S. Department of Veterans Affairs (VA), FOIA Service. You requested "A copy of the meeting minutes from the last four meetings of the National Advisory Council, a Dept of Veterans Affairs federal advisory committee, administered by Avery Ann Rock at DVA."

Your request was received by the VA FOIA Service on June 8, 2020 and was assigned FOIA tracking number **20-07181-F**. Please refer to this number when corresponding with our office about this request.

On June 9, 2020, your request was referred to and received by the VA Office of the Secretary (OSVA).

On June 10, 2020, I acknowledged receipt of your request and advised that I conducted a search of the GSA Federal Advisory Committee Act (FACA) Database located at <https://www.facadatabase.gov/FACA/apex/FACADatasets> and a search of a search of the VA Advisory Committee Management Office (ACMO) website for public facing records. I provided you with the hyperlink to the December 4, 2019 meeting minutes of the National Research Advisory Committee (NRAC) that were found on the ACMO website. In my letter I also advised that I contacted the Designated Federal Officer (DFO), NRAC to conduct a search for and provide me all records responsive to your request.

On June 11, 2020, the DFO provided this office with a total of 26 pages, Bates numbered (20-07181-F) 000001 through (20-07181-F) 000026, consisting of the following:

VA NRAC Meeting Minutes of June 5, 2019, Bates numbered (20-07181-F) 000001 through (20-07181-F) 000006, (6 pages);

VA NRAC Meeting Minutes of September 4, 2019, Bates numbered (20-07181-F) 000007 through (20-07181-F) 000012, (6 pages);

VA NRAC Meeting Minutes of December 4, 2019, Bates numbered (20-07181-F) 000013 through (20-07181-F) 000016, (4 pages); and,

VA NRAC Meeting Minutes of March 4, 2020, Bates numbered (20-07181-F) 000017 through (20-07181-F) 000026, (10 pages).

All information is provided in its entirety. No portions of the requested records have been withheld either in whole or in part.

FOIA Mediation

As part of the 2007 FOIA amendments, the Office of Government Information Services (OGIS) was created to offer mediation services to resolve disputes between FOIA requesters and Federal agencies as a non-exclusive alternative to litigation. Using OGIS services does not affect your right to pursue litigation. Under the provisions of the FOIA Improvement Act of 2016, the following contact information is provided to assist FOIA requesters in resolving disputes:

VA Central Office FOIA Public Liaison:

Name: Doloras Johnson

Email Address: vacofoiaservice@va.gov

Office of Government Information Services (OGIS)

Email Address: ogis@nara.gov

Fax: 202-741-5769

Mailing address:

National Archives and Records Administration

8601 Adelphi Road

College Park, MD 20740-6001

FOIA Appeal

Please be advised that should you desire to do so; you may appeal the determination made in this response to:

Office of General Counsel (024)

Department of Veterans Affairs

810 Vermont Avenue, NW

Washington, DC 20420

If you should choose to file an appeal, please include a copy of this letter with your written appeal and clearly indicate the basis for your disagreement with the determination set forth in this response. Please be advised that in accordance with VA's implementing FOIA regulations at 38 C.F.R. § 1.559, your appeal must be postmarked no later than ninety (90) days of the date of this letter.

Sincerely,

Ruthann

Parise 941640

Ruthann Parise
OSVA FOIA Officer

Digitally signed by
Ruthann Parise 941640
Date: 2020.06.12
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Date: 2020.06.12
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**Department of Veterans Affairs
National Research Advisory Council (NRAC) Meeting
Room 730, 810 Vermont Avenue NW, Washington, DC
June 5, 2019**

Minutes

Members Present

Young, David G., Chair
Bitsoi, LeManuel Lee
Farmer, Carrie M. (by phone)
Guccione, Andrew A.
Lee, Jerry S.H.
Lillard, James W.
Lima, Maria F.
Ling, Geoffrey
Lushniak, Boris
Maddox, Yvonne T.
McKinney, Jr., Ross

Members Absent

Catherine A. L. Wicklund

VA Staff Present

Rock, Avery, Designated Federal Officer (DFO)
Huang, Grant, Alternate DFO
Robinson, Rashelle, Alternate DFO
Ramoni, Rachel
Moragne, Jeffrey
Dorn, Patricia
Gurland, Jonathan
Singh, Hardeep
Souden, Maria
Byrne, James

Public Attendees

Anderson, Lauren
Charalambakis, Naomi
Starrs, Rick
Stewart, Julie
Taylor, German

Call to Order/Opening Remarks – Avery Rock, Designated Federal Officer (DFO); Grant Huang, Alternate DFO; Brig. Gen. David G. Young, Chair; Rachel Ramoni, DMD, ScD, Chief Research and Development Officer

Ms. Rock and Dr. Ramoni called the Committee to order at 9:07 a.m. as Dr Young, NRAC Chair, was delayed in Security. Ms. Rock was introduced as the new DFO for the committee and she provided statements regarding the committee, its purpose and the process for public comments. Dr. Ramoni welcomed and thanked the committee members for their service. She highlighted agenda items while describing key goals and objectives for the meeting including getting input on:

- 1) Electronic Health Record (EHR) Modernization and its impact on research – discussions and recommendations on how to mitigate those impacts will be an important area for the Office of Research and Development (ORD) going forward;
- 2) ORD Strategic Priorities on access to clinical trials, having substantial real-world impact of results and a priority related to making data work for Veterans;
- 3) Collaborations particularly with the Department of Defense.

Dr. Huang reminded the NRAC that some members will have terms expiring and requested that NRAC think about potential nominations. He solicited views from the NRAC on experience and expertise that would be valuable in addition to scientific and subject matter experts that would help with a diverse representation of health services, biomedical, clinical, rehabilitation, and other types of areas, such as informatics/information science and “Big Data”. With the current issues the VA and the nation are facing regarding the opioid crisis, suicide and limited mental health care access, it was suggested that special efforts be made to recruit a qualified mental health researcher to the NRAC.

Remarks from the Office of the Deputy Secretary – The Hon. James Byrne

While awaiting Mr. Byrne’s arrival, Dr. Maddox previewed the partnership discussion by describing a recent meeting at the Uniformed Services University that was also attended by Dr. Ramoni. At this meeting, topics focused on how to foster research collaborations with partners on the West Coast and in the Pacific. These partnerships involve DoD military treatment facilities and academic institutions in these areas. It was noted that given shared interests between VA and the Department of Defense (DOD), there may be some opportunities to pursue.

When Mr. Byrne joined the meeting, he thanked Council members for their service, noting the importance of federal advisory committees. He gave the top priorities for the Secretary which are:

- 1) Customer service – There is to be a focus on serving Veterans and those who serve the Veterans.
- 2) Implementation of the MISSION Act – While VA provides care in the community, consolidation of that care, making it more efficient, user friendly and helping providers will help add to the experience of care.
- 3) Modernization – Efforts are focused on Information Technology modernization across the country, improving activities involving the supply chain and financial management business systems.
- 4) DOD collaboration – VA has a natural relationship with the DoD that should be built up.

VA priorities on suicide prevention were discussed, especially regarding the need to address the stigma associated with mental health issues and seeking care.

NRAC members raised questions including how to obtain IT support for activities such as the Million Veteran Program (MVP). Mr. Byrne noted that VA has a new Chief Information Officer, Mr. Gfrerer, and encouraged talking to him.

NRAC Chair Dr. Young suggested the following recommendations which could be accomplished with no new resources:

1. Seek to expand the number of mental health professionals available to provide care for veterans by conducting a critical review of scope of practice limitations, and type of professional degree limitations acceptable for employment currently within the VA (e.g., PhD, PsyD and Masters in Counseling). Many states have expanded practitioner scope of practice limitations to address the critical shortage of mental health practitioners nationwide, especially in light of the opioid overdose epidemic. This would be similar to scope of practice expansion for nurse practitioners and physician assistants, optometrists and nurse anesthetists.
2. Address critically the barriers to care for Veterans, who should be encouraged to seek care for mental health issues, yet find negatives at their first encounter. For example, screening questions to obtain a permit or license to purchase a firearm often include a question such as "Have you ever sought treatment for a mental health problem?" This very question will dissuade veterans from seeking help as their legitimate concern is that answering in the affirmative may prevent them from exercising their Second Amendment rights. Further, a common concern within the active duty military force is that seeking help and receiving treatment ends up with a "Scarlet Letter" on their records which follows them from assignment to assignment even if the treatment was successful and has no further impact on duty performance.
3. Registries and various offices within the VA and the DoD working with post-deployment health concerns, e.g., Agent Orange-the Air Force Health Study, Gulf War syndrome and burn pit registries, seem to be managed by a multitude of offices. The stand-up of the Defense Health Agency (DHA) would seem to be an opportunity to bring these efforts together for a more unified and systematic approach, especially as relates to opportunities for clinical research.

Comments from the Advisory Committee Office (ACMO) and Ethics Training - Jeff Moragne, Director, ACMO & Jonathan Gurland, General Counsel Ethics Specialty Team

Mr. Moragne briefed the Council on the role of the Federal Advisory Committee Act and VA's efforts regarding its advisory committees. Additionally, the Council charter and balance plan were discussed and members were asked to review those documents. Dr. Young suggested that ACMO consider a summit for recognizing VA's contributions, particularly in research, that have brought substantial gains to the practice and understanding of healthcare to the benefit of all of our citizens.

Mr. Gurland provided the annual ethics training to NRAC members. He emphasized the role of special government employees and that members should feel free to call the Ethics Specialty Team with any questions. A copy of the VHA Code of Integrity will be provided to NRAC.

Discussions on EHR Modernization – Maria Souden, Ph.D., MSI Acting Director, VA Information Resource Center

Following a suggestion from the March NRAC meeting to discuss EHR activities, Dr. Souden was invited to provide an update on EHR Modernization (EHRM) efforts centering on the transition to Cerner and its implementation within VA. She noted that Seattle and Spokane will

receive the Cerner system first, by next March or April. The system will be implemented in a cycle around the country as a 10-year rollout. While 10 years is a long period, VA medical centers will have the opportunity to learn from each other over this time to help implementation go smoother.

Dr. Souden also discussed how the Office of EHRM has created 18 national councils that are tasked with specifying VA's requirements with the Cerner system. Councils cover clinical, ancillary support, and business and support services. Research is under the Quality Safety Value workgroup, and concerned with the quality of data and how they are used analytically to meet research goals. The research workgroup is composed of members representing ORD services. Near-term efforts of the research workgroup are focused on mitigation plans for any initial risks when going live at first. Longer term goals will address next generation application/product development to push research further. The workgroup also will have a "go-live" strategy to assess risks, implement mitigation strategies, assess effectiveness and impact, and will continue to refine the strategy for the next go-live. The issues the workgroup would like to address include: 1) data syndication; 2) standing up research to help improve the implementation; 3) opportunities to invest in quality research, with a goal of improving it.

NRAC raised questions including:

- Each research group has their own sets of data, legacies, etc. How will they be handled?
Reply: There is a reports & registries workgroup addressing this to look at all the different items. These items will be inventoried and accounted for and their owners identified.
- What happens to VINCI?
Reply: VINCI isn't going anywhere; it will work with Cerner data throughout the process. NRAC then further questioned whether there would be adequate infrastructure support.
- What does interoperability of systems mean?
Reply: Community care and other groups can be provided opportunities for interoperability; also interoperability with DOD is facilitated as Cerner is their contractor as well.

NRAC discussed the need to touch on these issues at future meetings with an eye to developing an approach to studying these impacts in a way that will not be too burdensome. NRAC was supportive of research on Cerner, its utility and impacts noting that it is primarily a clinical/billing platform. They indicated the importance of prioritizing data/research activities and needs, especially for "Big Data" research. We should not lose opportunities simply because they were not thought of initially.

2021 Proposed Priorities for ORD Budget – Rachel Ramoni, DMD, ScD

Dr. Ramoni presented recent ORD efforts on preparing the budget request and priorities for 2021. She highlighted ORD's three strategic priorities related to access to clinical trials, making real-world impact and having data work for Veterans, and provided brief updates on these priorities. Dr. Huang noted that written updates were provided to NRAC members as specified in the annual plan, and in the interest of time, welcomed feedback via email.

NRAC members followed with questions and suggestions including:

- Consideration should be given to the appropriateness of biomarker research in light of MVP efforts.
- There is a need to look at diversity in genomics/genetics research.

- Dr. Ramoni noted that while diversity considerations are a part of planned activities, it can be more clearly highlighted. An example of research results known to be a factor of a diverse population is to gain a better understanding as to why African Americans have a higher rate of prostate cancer.
- How can priorities be addressed in an environment of limited funds? Also, what is the impact on making the key priorities more visible?
- There is a need for mental health research efforts to be front and center. How can VA ensure mental health issues get an appropriate share of research funding?
- In context of the 21st Century CURES Act VA was left out; how can that be changed?
 - It was further noted that given VA's impact from its smaller research budget compared to NIH, VA needs to consider how to ensure research is included in overall budget discussions. How can decision makers be made to understand the impact of VA's translational research activities given return on investment?
- the VA ecosystem allows comparing the signaling cascades, phenotypes, etc. inherent within various health issues. How does VA leverage this system?
 - Patients own their own data under 21st Century Cures; VA has the opportunity to teach other systems about how to handle such issues
- Data/data science is a common link among all of the areas. Who else will partner to do the work, especially given VA's particular strengths in this area?
- There has been a tendency to look at things backwards. There needs to be a way to align funding with areas where there have been successes. For example, an evaluation of the portfolio should help with investing in those things that have been going well based on outcomes, while also turning to forward-looking projects.
- What can be done to trumpet where VA research has made a huge difference in healthcare for all Americans? What has VA done that no one else has done, and that wouldn't have been done elsewhere?
- ORD should consider engaging younger people in research; some beneficiaries of VA are members of underrepresented individuals and communities – how can we engage them into our system? Is there a way to formalize such programs within VA R&D?
 - This topic may be a good opportunity for collaboration with the NAAC and a potential area to explore. It was further suggested that a subcommittee on training/education be established.

Facilitating ORD Research Collaborations – Drs. Maddox and Ramoni

Discussion continued from earlier meetings regarding collaborations with others, including the DOD. It was suggested that ORD also needs to consider looking at the Public Health Service (PHS). The PHS has several qualities and priorities that align with those outlined previously. Another suggestion was to look at what is known about research activities and how well they reflect the populations they were intended to serve. What can ORD do to have researchers align with those groups?

The following idea was proposed: Pick 5 sites (e.g., locations where there is a VA and DOD healthcare facility (and possibly PHS site) and target their use of Cerner/EHR-informatics for opportunities for research collaborations. Such an approach may help with more proactive directions on requirements development. San Antonio, Seattle, Tidewater, Las Vegas and the Washington, DC regions were suggested. Following a request for priorities in 2021 from Dr. Ramoni, it was proposed that ORD should consider having a certain number of VA/DOD collaborations driven by EHR activities. Another consideration was to identify locations where there are VA and DOD sites to be focal points for doing data science research.

Questions arose regarding work in toxic exposures and whether future meetings should discuss recommendations from the National Academies for Science, Engineering and Medicine. Also, does ORD need to operationalize a response to that report? It was suggested that someone be invited from an appropriate DOD service or from the DHA to a future meeting to speak about it. NRAC members should provide input on the types of information they would like to hear at a future meeting. Another idea was for ORD to consider how to potentially include beneficiaries/children of veterans as future investigators interested in addressing problems faced by their parents. This topic was proposed as an agenda item for the next meeting.

VA Investigator Presentation - Hardeep Singh, MD, MPH – Chief, Health Policy, Quality and Informatics Program, Center for Innovations in Quality, Effectiveness and Safety, Michael E. DeBakey VA Medical Center

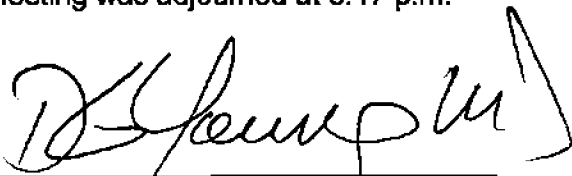
Dr. Singh presented his work involving the EHR and the related challenges and best practices within healthcare facilities. Examples highlighted multiple socio-technical issues that related to health IT safety implementation issues. His research suggested the need for more interagency operability and collaboration on best practices. Implications are related to diagnostic activities, medication overdoses and the clinician's roles in healthcare delivery. Activities should target regulatory and policy requirements.

Wrap-up and Adjournment

Closing comments from Dr. Ramoni and Dr. Young summarized activities for future meetings. Work on toxic exposures and bringing young investigators into VA research who have personal connections for doing this work were re-emphasized. It was also requested that ORD topic areas and funding amounts be presented to help with context on the ORD 2021 budgetary priority discussion. Regarding collaborations, the discussions related to DOD opportunities were raised. An attempt to identify agreements (e.g., in prostate cancer, suicide prevention, Cerner/EHR) and to identify what outcomes have been successful and noteworthy should be undertaken. The alignment of VA's efforts with the Defense Health Agency were also recommended as a focus for future discussion.

Public comment came from the National Association of Veterans' Research and Education Foundations regarding their and VA affiliated non-profit corporations being available to assist with any future collaborative opportunities.

The meeting was adjourned at 3:17 p.m.



David G. Young II, M.D., FACP, Brig. Gen. USAF (Ret.)
Chair, National Research Advisory Council

**Department of Veterans Affairs
National Research Advisory Council (NRAC) Meeting
Room 104, 1100 First Street, NE Washington, DC
September 4, 2019**

Minutes

Members Present

David G. Young, Chair
Carrie Farmer
Andrew Guccione
Jerry Lee (by teleconference)
James Lillard
Maria Lima
Boris Lushniak
Geoffrey Ling
Yvonne Maddox
Ross McKinney
Catherine Wicklund

Members Absent

Lee Bitsoi

VA Staff Present

Grant Huang, Alternate DFO
Rashelle Robinson, Alternate DFO
Rachel Ramoni
Vicky Davey
Molly Klote
Maria Souden
David Atkins
Wendy Tenhula
Karen Block
Scott Duvall
Patricia Dorn
Amy Kilbourne

CALL TO ORDER/OPENING REMARKS

Grant Huang, DFO; Rashelle Robinson, Alternate DFO; Brig. Gen. David G. Young, Chair; Rachel Ramoni, DMD, ScD, Chief Research and Development Officer

Dr. Young, NRAC Chair, called the meeting to order at 9:05 am. Dr. Huang introduced himself as DFO for the meeting in place of Avery Rock who was unable to attend the meeting. Rashelle Robinson served as the alternate DFO. Dr. Huang gave opening statements regarding the committee, its purpose and the process for public comments. Dr. Young then called for introductions from committee members.

Dr. Young turned things over to Dr. Ramoni for her opening remarks and ORD updates. She thanked committee members for their service, outlined the purpose of the meeting and reviewed

discussions from the prior NRAC meeting. She also highlighted budget priorities and VA Data Commons activities and plans. Other Office of Research and Development (ORD) activities included the PREVENT Executive Order on preventing Veteran suicide, field listening tours to learn about the challenges faced by research offices and investigators in doing research, and field engagement activities involving larger meetings with research administrative officers and Institutional Review Board and Research and Development Committee managers. She further discussed how NRAC could help in the current meeting by going in depth with ideas previously generated to determine if and how to move forward on them. Specifically, some areas to discuss as noted in the agenda included: Electronic Health Record modernization; National Research Action Plan in relation to traumatic brain injury (TBI) and post-traumatic stress disorder (PTSD); military exposures; and considering how children of Veterans may possibly be future investigators. In this context, Dr. Ramoni indicated the importance of NRAC in providing advice to the Secretary and research matters. A reminder was also given regarding NRAC member terms expiring and the need for nominations.

Dr. Ramoni focused on reviewing activities from the three ORD strategic priorities, including 1) increase Veteran access to high-quality trials, 2) increase real-world impact of VA research and 3) putting VA data to work for Veterans. She had ORD staff leading the efforts to provide updates.

Access to high-quality trials: Dr. Huang described how efforts were focusing on the workflow to help industry partners understand how to work with VA. Specifically, Standard Operating Procedures (SOPs) were being drafted by a workgroup. A recent accomplishment was approval for centralizing non-disclosure agreements as an alternative to doing them at individual VAMCs. Additional activities include gathering input from outside federal and VA entities as part of subcommittee efforts.

Real-world impact: Dr. Kilbourne described a focus on reducing three major barriers to real-world impact that include 1) alignment of research with VA national priorities, 2) creating and promoting incentives for researchers to validate their discoveries and 3) investigator incentives to conduct implementation research to ease translation. The presence of ORD/QUERI along with VHA Finance, the Office of Policy and Planning, and the Office of Strategic Integration were noted in efforts to operationalize the Evidence-based Policy Making Act. Also, mention was given on a Request for Applications (RFAs) for validation of preclinical discoveries and mechanisms and the development of SOPs for a national resource center(s) to facilitate implementation activities with the Cooperative Studies Program. HSR&D also is taking lead on multiple RFAs related to implementation science, including a recent initiative that enables investigators to work with existing providers toward adoption and testing of interventions.

Putting VA data to work for Veterans: Dr. Duvall described three areas of activity that include 1) building infrastructure, including final signatures on data comments, imminent IT approvals and an upcoming meeting that will look at next 3 to 5 years of internal infrastructure; 2) Presidential Innovations Fellow program, which allowed VA to help write and embed VA goals into National Artificial Intelligence Plan and other national policy initiatives; and 3) potential data partnership initiatives for predictive modeling to test and determine capabilities across different health care institutions.

Dr. Young asked that these points on the ORD strategic priorities be summarized in the minutes and codified for the annual report.

NRAC Discussion

Discussions in response focused on the importance of behavioral and mental health issues and suicide prevention in particular. The limited availability of psychiatrists, psychologists and other mental health professionals was noted. While access has been studied, a greater need was getting people to high quality providers who use evidence-based treatments. Comments were raised on the importance of investing in these areas. In addition to suggesting that NRAC help with efforts in this area through its recommendations, a proposal was made to develop a subcommittee on suicide prevention research. Dr. Farmer, Ms. Wicklund and Dr. Young offered to help. A separate more focused briefing for interested individuals was suggested. Dr. Maddox also mentioned a DOD strategic plan in this area and an upcoming meeting in October in which NRAC members were invited to participate. Satellite sessions on suicide and suicide prevention were to occur.

Regarding NRAC membership, it was noted that NRAC stands out on diversity, representing women, minorities, underserved and Veterans. To help align membership with priorities, it was requested that ORD be specific with the types of expertise needed to allow NRAC to be helpful with potential nominees.

Additional general discussion followed related to the following issues:

- Inability to recruit qualified individuals from the various health professions and other issues that hinder recruitment
- The state of ORD research vis a vis what types of new processes, infrastructure, support
- Communicating research
- Implementation science
- Incentives for doing research that solves problems faced by frontline clinicians

MILITARY AND TOXIC EXPOSURES RESEARCH

Dr. Vicky Davey, Associate CRADO for Epidemiology and Public Health

Dr. Davey presented on military exposures research related to: challenges; present state; ORD funding mechanisms; and potential future directions. Points raised included the serious limitations to studying exposures, including limited or nonexistent measurement, combination exposure, diluted identification of exposed cohorts, lack of understanding of toxic effects of substances under military conditions, the overlap of health effects of toxic exposure and diseases of aging, and constituents who believe they already have answers to toxic exposures. Dr. Davey also noted distrust of VA research among Veterans, especially during and post-Vietnam era. Partnerships and resources, including data sets were covered, to help the committee with considering opportunities.

NRAC Discussion

NRAC questions and discussions centered on the nature of distrust and whether it was related to eligibility or exposure and eligibility for benefits. Others described their personal and professional experiences, including a schism between benefits and medicine, misperception among dual beneficiaries (DOD and VA) related to distribution of money, and perceived institutional rivalry between DOD and VA. Perspectives were raised on occupational health issues and where responsibility resides—i.e. DOD, VA, OSHA, Dept of Labor, HHS, NIOSH—in

addition to how issues can be politicized and needed to deal with cultural shifts in research. Other questions addressed how much of efforts were focused on suicide prevention and the challenges associated with the ability to know locations of Veterans and working with other partners.

Discussions closed with questions on the type of expertise who can help with NRAC efforts in this area. Some ideas included individuals who could help with identifying high-priority diseases and conditions, oncology, understanding of PFAs (perfluoroalkoxy alkanes) and partnerships with NIEHS. Dr. Ramoni asked the group to think about and submit suggestions for new members to NRAC group and toxic exposures group.

VA/DOD/OTHER COLLABORATIONS

Dr. Molly Klote, Director, Office of Research Protections, Policy & Education

Dr. Klote briefed the committee on efforts to update the VA/DOD research guide book, a project that has included bringing together multiple stakeholders. Among the challenges revealed during meeting among stakeholders: unacceptable delays in IRB approvals; unacceptable delays in establishing agreements; variability regarding policy limitations; limited or non-existent preplanning, and no repository/examples of successful collaborations. Dr. Klote presented to NRAC a draft document describing 10 myths of collaboration. This document will be published electronically and discussed at an upcoming cyber seminar.

It was suggested that a similar briefing be considered for the National Academic Affiliation Council. Questions on budget requirements were also raised in which the reply was that it was part of next steps to determine.

A core/central authority was identified as a critical factor to success. Furthermore, Dr. Ramoni would be VA stakeholder, but that someone from DOD would need to be identified. Dr. Huang reminded NRAC that key recommendations to the Secretary would need to be generated soon and this point would be noted in the minutes.

ELECTRONIC HEALTH RECORD MODERNIZATION

Dr. Maria Souden, Dr. David Atkins – Office of Research and Development/Health Services Research and Development Service

Dr. Atkins gave updates from last NRAC meeting on Cerner transition, including the following goals to ensure that the unique needs of research are considered: understanding risks; identifying solutions; building awareness about impact. Dr. Souden also highlighted work that remains in: migrating and mapping data into Cerner; sustaining availability of EHR data for reuse; data governance and data access; impact on research administration and support; and ORD Strategic Initiative for Research/EHR Synergy.

NRAC Discussion

This topic raised several questions and concerns regarding not only the activities of the migration but the impact on quality research for VA. Specific issues were related to data flow/operations, access to the data, resources for handling the transition for research, the need to focus on the validity of research that would arise from use of Cerner, whether any strategies were in place regarding unstructured data, how clinicians/investigators were going to be informed of how data could be obtained/used and the need for efforts for focus on quality comparisons. Members indicated their experiences and noted limitations of Cerner/EHRs

particularly for research purposes. NRAC suggested that VA needs to work on a central strategy for use of the EHR as it relates to research and the research community who would be reliant on its data. The need for resources to properly handle it was also noted as an area NRAC should include in its recommendations.

ENGAGING/RECRUITING NEW INVESTIGATORS

Committee

Dr. Huang reviewed the prior NRAC meeting discussion related to engaging dependents of children of Veterans to be future VA researchers because of their potential vested interest.

Questions were raised about whether good data points existed. Specifically, what are influencers and drivers of children entering into science? Do data exist that suggest that this approach would work? No data were known by ORD staff.

A comment suggested that focusing on the children of Veterans would be an interesting idea compared to other diverse groups, and it may be a powerful idea; however, we may need to go after diversity more. The remaining discussion revealed multiple suggestions and concerns, among them:

- Student debt and loan forgiveness as recruitment tools—student debt is repelling potential talent
- How to attract among the economically disadvantaged students
- Current VA loan repayment initiatives are not open to research positions
- Cost of education and its impact specific to diversity in the sciences
- Lack of funding opportunities that make science careers unattractive and not sustainable
- VA research funding opportunities that are more consistently available
- ORD career development funding, and funding for unfunded projects
- Loss of administrative staff (regulatory et al.) who are recruited into university/academic environments where there is more money
- Potential to use career VA scientists as volunteer mentors for those doing unfunded research
- How to increase more interest in STEM careers, generally

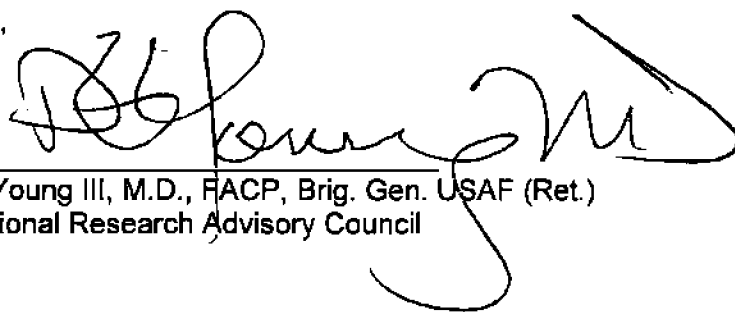
Some suggestions for ORD actions included considering a summit of investigators who have shown impact and presenting to others on how to do work with VA, especially in clinical research where treatments are a focus.

PUBLIC COMMENT, FUTURE NRAC ACTIVITIES

Dr. Huang noted that there were no public comments. The next NRAC committee meeting would be held December 4 and that members should think about concrete recommendations for annual report.

The meeting was adjourned at 3:15 p.m.

Submitted,

A handwritten signature in black ink, appearing to read 'D. G. Young III', written over a horizontal line.

David G. Young III, M.D., FACP, Brig. Gen. USAF (Ret.)
Chair, National Research Advisory Council

**Department of Veterans Affairs
National Research Advisory Council (NRAC) Meeting
Room 104, 1100 First Street, NE Washington, DC
December 4, 2019**

Minutes

Members Present

David G. Young, Chair
Lee Bitsoi
Carrie Farmer
Jerry Lee (by teleconference)
Maria Lima
Boris Lushniak
Geoffrey Ling
Yvonne Maddox (by teleconference)
Catherine Wicklund

Members Absent

Andrew Guccione
James Lillard
Ross McKinney

VA Staff Present

Avery Rock, Designated Federal Official (DFO)
Grant Huang, Alternate DFO
Rashelle Robinson, Alternate DFO
Wendy Tenhula
Carlton Andrews
Maria Souden
Uben Mendie
Karen Seigel
Patricia Dorn
Amy Kilbourne
Theresa Gleason

Public

Tran Hawk

CALL TO ORDER/OPENING REMARKS

*Avery Rock, DFO; Grant Huang, Alternate DFO; Rashelle Robinson, Alternate DFO;
Brig. Gen. David G. Young, Chair; Wendy Tenhula, Deputy Chief Research and
Development Officer*

Dr. Young, NRAC Chair, called the meeting to order at 9:10 am. Avery Rock introduced herself as DFO for the meeting. Dr. Huang and Rashelle Robinson served as the alternate DFO's. Avery Rock gave opening statements regarding the committee, its purpose and the process for public comments. Dr. Young then called for introductions from committee members and discussed the agenda. The minutes from the last meeting were approved.

Dr. Young turned things over to Dr. Tenhula for her opening remarks and ORD updates. She thanked the departing committee members for their service and noted that the members will receive their signed appreciation certificates from the Secretary. Dr. Tenhula also thanked the committee members who committed to serving an additional term. Outcomes from a recent Government Accountability Office (GAO) review as to how the Office of Research and Development (ORD) set priorities for its funded research were summarized. It was noted that no findings came from the GAO report. Additional ORD accomplishments were highlighted in the annual report provided to NRAC members. She informed the members that ORD is considering its organizational structure and provided some updates on the PREVENT Executive Order on preventing Veteran suicide. She further discussed moving forward and the importance of NRAC in providing advice and input to the Secretary, ORD and the entire agency on research matters and ensuring great work. Dr. Tenhula ended with an introduction of the new ORD Director of Communications to help with the new ORD strategies.

ORD Communications: Ubon Mendie, Director of Communications, spoke about having more public affairs representatives and training investigators on how to better communicate while also aligning VA/ORD priorities. He discussed how the academic affiliates spoke more about VA research. He stated that if ORD can speak up more, it can help to change the perceptions that academic affiliates are doing most of the VA work. Mr. Mendie posed some questions to the NRAC for their advice and input on topics to include:

- How do we impact Veterans and Americans?
- Why we do what we do?
- How to communicate all research studies from a broader perspective?
- Suggestions on how to advertise the successful partnerships of VA and Academic Affiliations.

Real-world impact and NRAC Discussion: Dr. Kilbourne provided updates regarding the Real- World Priorities and requested feedback and input from the NRAC. Dr. Young emphasized that the VA does research that no one else would do and expressed that what is being done has great impact for all Americans. Dr. Lushniak reflected on his attendance at a NATO conference and explained that other parts of the world envy how special the VA is to have a separate and dedicated entity for Veterans. He also posed a

question on how do we change the lives of Veterans, their families, and society? Dr. Ling indicated that VA Investigators have academic affiliations and areas like chronic traumatic encephalopathy (CTE) research is very well known, but no one ever hears that it's VA research and that the VA is a source of "pride and swagger". Dr. Young suggested considering VA Choice ads as one way to advertise research work being conducting by the VA and that it is an important discussion to consider. Dr. Bitsoi suggested more diversity and inclusion as he stated that there are unique opportunities to highlight VA diversity. Dr. Maddox emphasized better awareness of the Million Veteran Program (MVP). Ms. Farmer stated that a lack of trust is a barrier and that there is an advantage when affiliates are involved. She also added that avoiding a self-serving VA agenda helps with perceptions of legitimacy. Dr. Kilbourne asked NRAC if they were in support of efforts to use case study with precision oncology? Dr. Ling asked what quality management tools would be used? Dr. Kilbourne's reply was to monitor the use and evaluate if people are utilizing the test and to look at the process of care from a systemic level. Dr. Wickland suggested looking at workforce issues such as genetic counseling. Dr. Young stated that genetic testing can be expensive and that often time things can be inappropriately ordered. He further stated that clinical transformation needs to be looked at. Dr. Lee asked if timeframes would be used as a factor to be examined such as pre/post FDA approval or pre/post 2016 retrospective look?

Annual NRAC Report & Recommendations

Avery Rock and Dr. Huang presented the annual NRAC report and asked the committee to provide a grade on appropriate portfolio balance and program management. Dr. Huang discussed recommendations and actions summary. Ms. Rock discussed and reviewed the SMART template for making recommendations to the SECVA. Dr. Young discussed the previous September minutes and recommendations with the members. He further discussed the Electronic Health Record (EHR) to include IT issues, privacy, and the Big Data DOE efforts.

Dr. Huang discussed future meetings and asked the committee members for suggestions for possible meeting sites and topics. The NRAC suggested joint meetings at VA facilities such as Stanford-Palo Alto, Tampa, Albuquerque, as well as VA research programs that may be struggling such as Chicago and Miami. NRAC also suggested that ORD present challenging cases from these facilities to better understand situations that researchers and research offices face and how NRAC can potentially advise SECVA. Another question was raised on whether there can be a focus on smaller sites that may need to grow their research departments. Other suggestions were that Tech Transfer report revenues in the NRAC report and a list of other FAQs that can better be aligned with the priorities. Dr Huang reported that a tutorial on "how

to propose research of benefit to Veterans for those from outside the VA" was expected to be completed by February 2020.

Electronic Medical Record Modernization Update: Dr. Maria Souden presented slides and updates regarding the Cerner transition. Dr. Souden asked for suggestions and input from NRAC. She spoke about the "Death by a Thousand Clicks" article in Fortune Magazine, the Joint Legacy Viewer experience with DOD/VA efforts in San Antonio, TX., and the development of a white paper for the Office of Electronic Health Record Modernization. A question was asked regarding what is the biggest barrier to getting research done and what should be the major thing to be addressed? NRAC expressed significant concerns about the next generation workflow and lost opportunities if the Cerner transition does not properly consider research requirements and incorporate research appropriately into the systems design. Dr. Souden also highlighted work that remains in: migrating and mapping data into Cerner; sustaining availability of EHR data for reuse; data governance and data access; impact on research administration and support; and ORD Strategic Initiative for Research/EHR Synergy. They further discussed that the Electronic Health Record Modernization (EHRM) should be of high priority to the Secretary. NRAC indicated that IT support and protected time are also key reasons for weaknesses in the ability for research to be successful.

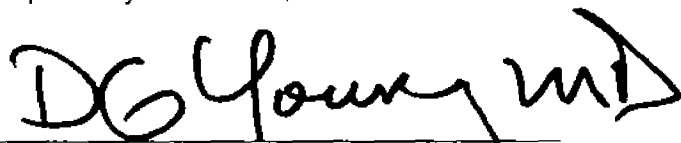
Public Comments: It was suggested by Mr. Tran Hawk that the NRAC report on page 37 should be corrected regarding the role of the VA Non-Profit Program Office.

Finalize Recommendations to Secretary: Dr. Young led the committee members in a discussion of three recommendations for the SECVA to consider. Dr. Huang asked to help with the initial draft based on the NRAC comments/minutes which would then be distributed to the Chair and committee members to be finalized.

The next committee meeting will be held March 4, 2020. The meeting will consist of five new committee members and the new selected NRAC Chair, Dr. Geoffrey Ling.

The meeting was adjourned at 3:30 p.m.

Respectfully Submitted,

A handwritten signature in black ink, reading "DG Young III". The signature is fluid and cursive, with the "III" written in a stylized manner.

David G. Young III, M.D., FACP, Brig. Gen. USAF (Ret.)
Chair, National Research Advisory Council

Meeting of the National Research Advisory Council (NRAC)
Department of Veterans Affairs
Office of Research and Development
810 Vermont Avenue, N.W.
Washington, DC 20002
Wednesday, March 4, 2020

MEMBERS PRESENT:

Geoffrey Ling, M.D., Ph.D., Colonel, US Army (retired), Committee Chair
Steven Dubinett, M.D.
Carrie M. Farmer, Ph.D.
Matthew Kuntz, J.D.
Jerry S.H. Lee, Ph.D.
Maria F. Lima, Ph.D.
Ross McKinney, Jr., M.D.
Paula Schnurr, Ph.D.
Catherine A.L. Wicklund, M.S.

MEMBERS ABSENT:

Sanjay Doddamani, M.D.
James W. Lillard, Jr., Ph.D., MBA
Ronald Poropatich, M.D.

ALSO PRESENT:

Christopher Syrek, Deputy Chief of Staff
Jeff Moragne, ACMO
Rachel Ramoni, CRADO
Wendy Tenhula, Deputy CRADO
Avery Rock, DFO
Grant Huang, DFO Alternate
Rashelle Robinson, DFO Alternate
Larry Mole, Chief Consultant VHA
Ken Myrie, CSR&D
Suma Muralidhar, Million Veteran Program
David Atkins, HSR&D
Theresa Gleason, CSR&D
Karen Lohmann Siegel, RR&D
Patricia Dorn, RR&D
Marisue Cody, ORD

PUBLIC:

Rick Starrs, NAVREF

Welcome/Opening Remarks

Dr. Ling, NRAC Chair, called the meeting to order at 9:03 am. Avery Rock introduced herself as DFO for the meeting. Dr. Huang and Rashelle Robinson served as alternate DFOs. Avery Rock gave opening statements regarding the committee, its purpose and the process for public comments. Dr. Ling then called for introductions from committee members including new members and discussed the agenda.

Dr. Ramoni updates the committee on the Office of Research and Development through its three strategic research priorities:

- (1) Increasing Veterans' access to high-quality clinical trials. Updates include: A two-year effort between VA, industry, and NAVREF called ACT for Veterans, Access to Clinical Trials for Veterans enacting a system-wide research review platform; a partnership with NCI and Prostate Cancer Foundation to fund enrollment sites
- (2) Increasing the substantial real-world impact of VA research. Updates include: Funding has been provided for toxicology studies as well as through the Tech Transfer Office for inventions. QUERI has been working with Finance across VA and VHA to rate levels of evidence in accordance with the Evidence Act to ensure policies are evidence-based.
- (3) To put VA data to work for Veterans. Updates include: VA Data Commons will be hosted for approved researchers to be given access to deidentified data from MVP and a phenotyping library is also in the works; the National AI Institute was chartered and will focus on policy and partnerships for AI; and cross-cutting clinical priorities continue including work on suicide prevention, precision oncology, PTSD, pain and opioids, Gulf War Illness, military exposures, and traumatic brain injury, among others.

Chairman Ling mentions that it is remarkable the amount of studies the VA is able to research with an approximately \$800 million budget. Chairman Ling also remarks that the VA Health System is the largest federal integrated health system in the country and requests that the committee think of ways in which they can help to improve it.

Jeffrey Moragne, Director of ACOMO, Advisory Committee Management Office

Jeffrey Moragne, Director of ACOMO, welcomes the committee members back, welcomes new members of the committee, and informs the committee he is there to answer any questions related to FACA.

Mr. Moragne stressed the impact Executive Order 13-875 has and will have on VA advisory committees. He notes that by eliminating the Fraud, Waste, and Abuse committee, as well as MyVA, they were able to maintain the proper ratio within VA's network of advisory committees. He warns that discretionary committees may be terminated at will and that even statutory committees are not immune from potential termination.

He reminds the committee members that they can provide opinions to legislative bodies but must make it absolutely clear that they are providing those as a private citizen, not as speakers for the committee.

Mr. Moragne details that FACA applies anytime the committee meets and anytime committee business is being conducted. He mentions that a Designated Federal Officer (DFO), or alternate DFO, must be present while the committee is conducting official business. He reminds the committee that 90 days after the Chair has signed off on a meeting it is available to the public. He notes that for a committee to be official there must be a quorum present (51% or more members). He notes that members can meet privately if they are doing preparatory work in the form of subcommittees, focus groups, and work centered on organizing (i.e. travel arrangements) and administrating, rather than making committee recommendations.

Mr. Moragne goes over best practices and forums, requesting that members pay close attention to their calendars, study their charter to know and understand their role, organize themselves into subcommittees, plan meetings intelligently to include opportunities for discussion, collaborate across VA committees through DFO to DFO coordination, take advantage of VA resources such as the VA Library Service, reach out to subject matter experts, conduct field visits, and to always contact ACMO when unsure of a FACA-related question.

Christopher Syrek, Deputy Chief of Staff, VA Priorities

Christopher Syrek, Deputy Chief of Staff, introduces himself to the committee and conveys the support of the leadership team.

Mr. Syrek lists the priorities of the Secretary. The first of which is to improve the customer service at the VA by helping veterans to get a "yes" when they come in requesting and using services. The Secretary believes that by reducing the administrative and bureaucratic problems that existed within the agency, services are more streamlined to more effectively serve veterans. Trust scores have risen from the mid-60s from before the current Secretary to 74% today, and to 88% for outpatient services for the last 90 days. Mr. Syrek notes that it's also important to create an internal customer service culture within the agency that promotes the VA as a world class employer. Since the Secretary has arrived, the VA has gone from 17th out of 17 large federal agencies to 6th in the annual best places to work survey.

Mr. Syrek discusses the second priority, implementing the MISSION Act. Beneficial results from the MISSION Act, passed in 2019, have included the expansion of the community care program allowing veterans to seek treatment at urgent care facilities, reimbursed by the VA, allowing greater treatment access and reducing the burden on emergency rooms in both the VA and community overall. The MISSION Act is also actively working on expanding caregiver program benefits from post 9-11 veterans to veterans of all eras, which is expected to be published in the Federal Register in the near future.

The third priority of the Secretary is to replace the EHR system with VHR developed by Cerner. The goal is to link a veteran's record with DoD from when they leave the service to the VA, also integrating with community care providers and pharmacies. The VHR pilot program, originally scheduled for rollout in Spokane in March 2020, has been delayed slightly but should be rolled out within the next few months.

The fourth priority of the Secretary is to transform more business systems by improving IT, streamlining parts of the Agency, modernizing the appeals process for Veterans and their families, using digital services for financial management, and improving on logistics supply chains, among others. The Forever GI bill required an overhaul of 32 technical systems, which the VA was successful in completing.

Mr. Syrek also notes that they are working on ways to improve care for women veterans. Currently 41 percent of eligible women veterans are enrolled in VA services, a change from 420,000 women in 2014 to 545,000 today, which suggests that women veterans are enjoying the services VA is providing. Several key VA Secretary-appointed positions are held by women, reflecting the dynamic of change seen in women veteran enrollment. The budget for gender-specific services for female veterans has increased by 9 percent, also reflecting this change and underlining women-veteran care as a priority.

The President's budget for FY2021 is an increase of 10% from last year, totaling \$243 billion. VA plans to hire an additional 14,000 employees, over half of which will be clinicians (physicians, nurses, technicians).

Some of the budget highlights noted:

- \$10 billion for mental health
- \$313 million for suicide prevention
- \$1.3 billion for Telehealth
- \$626 million for women-specific care
- \$504 million to continue to address the opioid crisis
- \$75 million for precision oncology

Committee discussion included requests for commitment of IT access and IT resources, to which the Deputy responded that they are working on ways to allocate more money for that and is on the Secretary's radar. Chairman Ling noted the importance of research and a desire to see a significant increase in funding provided for research. Mr. Kuntz pointed to the importance of research in suicide prevention and Mr. Syrek pointed out that given that almost 75 percent of veterans who commit suicide are not enrolled in VA services, and part of the Secretary's biggest priorities is finding ways to reach veterans through the community before any final tragic act occurs.

Dr. Theresa Gleason, Director CSR&D, ORD Suicide Prevention and Q&A

Dr. Theresa Gleason talks about the difficulties associated with suicide prevention; although the VA is lauded as having an excellent program, not much has changed in terms of the numbers of suicides in the veteran population. The amount of attention this matter has received should be seen as an opportunity to really make a difference with an all-out, all-government, all-hands on deck approach recommended. Dr. Gleason also notes that we need to remember that it is not just a mental illness, it is also medical and behavioral illness and the risk factors associated should be addressed accordingly.

Dr. Gleason believes more studies should be conducted, infrastructure, investigators, and the scientific community needs to be built and developed in order to properly look at the complexity, scope of this problem and the question of how do we properly address it.

Some efforts noted by Dr. Gleason to address this task:

- A research core in Portland developed by Steve Dobscha that aims to systematically build resources across the VA. Systematic evidence review with an active database of clinical trials available.
- New agreement entered into with Army STARRS, allowing access to their data-rich environment which will help to answer questions regarding suicide prevention, risk factors, and interventions.
- Within the ORD, the Office of Mental Health's Suicide Prevention Program can provide an on-the-ground perspective from the clinical side. Dr. Gleason notes that by knowing what they need answers to will aid the committee in developing the right questions to ask of the scientific community in order to help them.
- Expanded efforts and support of new pilot studies through the SPRINT core.
- Support of extension of genetics queries and Million Veteran Program (MVP). Use of their data analytics power to query into suicide prevention in the veteran population.
- A plan to publish a new series of requests for applications.

In addition, as part of the PREVENTS initiative issued in March of 2019 a national research strategy has been developed. This includes risk identification, plan development and attack course, prevention and intervention through clinical trials and clinical research, implementation, what changes in the research findings into actual practice, data management and integration. Coordination will continue across federal agencies as the research strategy is enacted and outcomes are measured, and the strategy itself is fluid and open to change.

Member discussion and Q/A included:

Whether targeting of un-enrolled high-risk veterans is part of the PREVENTS recommendations and ORD's efforts (response: it must be included in the national strategy and educating un-enrolled individuals who are veterans but not in VHA on how they can go about seeking enrollment and help is critical); whether CSR&D uses the diathesis of stress model (no studies are currently using it; rather they're focused on risk identification, risk-prediction modeling, the

use of data, and investments in new clinical interventions); that it would be good to know the impact of suicide prevention within the context of clinical initiatives such as telemedicine and the homelessness problem by looking at before and after results (Dr. Tenhula and Dr. Atkins point to efforts that are currently in place to do just that, such as engagement with clinical program offices like the Office of Mental Health and Suicide Preventions, as well as individual programs like REACH VET (a program that utilizes predictive analytics to identify and provide targeted services to high-risk veterans), and a homelessness suicide work group that is specifically looking at research questions around suicide related to homelessness.)

The committee recommended that a subcommittee should be formed to delve deeper into issues surrounding suicide prevention, with recommended objectives to be framed and presented along with recommended subcommittee memberships at the next meeting by the four initial subcommittee members: Paula Schnurr, Jerry Lee, Carrie Farmer, and Matthew Kuntz.

Dr. David Atkins, Director of HSR&D, Electronic Health Records Modernization (EHRM)

Dr. Atkins updated the committee on modernization efforts, noting several areas of concern for research: Millennium (new version of CPRS), ensuring that researchers that need to touch the electronic record will be able to do that. Building new functionality through Cerner called "Power Trials" aimed at improving the ability to conduct clinical trials and increasing the visibility of these trials to potential veteran applicants. "Healthy Intent," equivalent of a corporate data warehouse where data from DoD and VA merge. He also notes that the implementation of clinical trials in Spokane have been delayed until October to allow time for the system to be updated to the point where personnel can train on it before it goes live.

EHRM goals and objectives include maintaining a continued ability to interact with the EHR in projects. This includes working out logistical issues around assigning permission levels to interact with different levels of sensitive data. Maintaining access to EHR data as the new system is developed. This includes finding out which data would be lost on the new system and then finding ways to merge it appropriately.

Five categories of emphasis:

- Communications: Improve communication between HSRD and OEHRM with regular meetings and identify the proper points of contact.
- Resources: Acquire resources from Cerner that will help get people on their team working with researchers to figure out how to solve identified problems, as well as acquire researchers from Booz Allen Hamilton.
- Access: Develop rules that will govern who is allowed access to what by mapping out all the different roles that researchers have.
- Syndication: Bring data from Cerner into the corporate data warehouse environment, understand what's different between the data structures in the two systems, and develop education and training tools for researchers.

- Training: Develop training for people with all different roles with the ideal training situation to include a test environment where researchers can get in and focus on what they will be faced with.

Discussion and Q/A

Discussion among members regarding identifiable versus de-identifiable data (all data can be deidentified), has the VA evaluated other large implementations of VHRs (to a degree, yes), an off-site visit to Seattle was recommended, and better collection of data through training the front line to gather data as intended for a unified national data set, rather than just a local one.

Dr. Suma Muralidhar, Director of Million Veteran Program, MVP and Q&A

A video was played which covered some of the highlights and testimonies from veterans who have participated in the program.

Dr. Muralidhar discussed the program in depth, recognizing that it is well-aligned with the shared objective of putting VA data to work for veterans in pulling clinical data, genetic information, lifestyle information, and environmental exposures to create algorithms that can provide precision treatment for veterans where appropriate.

The goal of MVP when initiated in 2011 was to enroll one million veterans. Since then roughly 90 to 100,000 have enrolled per year and currently MVP is on pace to reach the million veteran mark by 2021. Recently an additional goal of getting to 100 scientific projects funded by the end of 2021 has been added.

Dr. Muralidhar goes over the structure of MVP, consisting of an office of research and development, an executive committee that reports to the program office, and subcommittees that are created under the executive committee as needed. Several coordinating centers manage the implementation of various core functions around recruitment, enrollment, data generation, and scientific operations.

Veterans who participate in the program fill out a consent form and HIPAA authorization, complete a couple of surveys that detail their health history, military exposures, lifestyle, and nutritional status, they provide one tube of blood to be used for any research, and they provide access to their current electronic health records as well as agree to be contacted in the future. Over 825,000 veterans have enrolled, and an online portal was enacted in 2019 to facilitate enrollment. Alternatives to blood samples, such as saliva collection, are being considered as a backup. An inter-agency initiative between the MVP and DoD has been agreed to open up MVP to DoD beneficiaries in the Millennium Cohort Study. MVP MIND, a sub-cohort of MVP, is another initiative enacted to focus on mental health and substance abuse and calls on a collaboration between MVP, CSP, and CSR&D services and has a goal of enrolling 50,000 veterans in five years.

To qualify for MVP enrollment one only needs to be able to be enrolled in the VA health care system. Enrollees are made up of 91% male, it's racially and ethnically diverse (20% African American, almost 7% Hispanic), 60% of the cohort are above the age of 60, and most service areas are represented.

All DNA samples are stored, isolated, and every sample is genotyped and associated with validated phenotypes. MVP data universe includes self-reported/survey data, molecular data from the biospecimens, passive data collection from DaVINCI, as well as NDI and CMS data provided to MVP, and efforts are being made to gain permission from DoD to use their data as well. Affymetrix Axiom Array is used to genotype and a specific chip has been designed for enhanced content for African Americans and Hispanics. All work is performed within the GENESIS environment within the VA.

Discussion and Q/A

Member discussion included how results are structured (individual result returns to veterans are being considered), whether there are plans to include co-genomics, wearable devices to obtain real-time data, and whether internet kiosks/online-device sign-ups from within VA waiting rooms are being considered (all are options that MVP is looking into), as well as whether variant information on underrepresented populations can be funneled back into general populations (there are ongoing discussions for how to handle that in the future).

Dr. Ken Myrie, Program Manager for CSR&D, Precision Oncology and Q/A

Dr. Myrie provided background on Precision Oncology. In 2016 the National Precision Oncology Program was created, focused on providing the most appropriate treatment for the right patient at the right time. Its focus at conception was to create a tumor oncology board to study the most difficult cases while educating oncologists on how to take care of veterans based on NGS testing.

Precision Oncology seeks answers to questions such as: Why does one patient with an identical cancer do better than another; what is the molecular makeup of tumors that makes them respond differently; and are the answers contained in personal genetic mutations?

Since 2019, over 10,000 samples have been sequenced. Over 200 projects were funded in 2019 in cancer research totaling \$59 million. Major funding has come from the Prostate Cancer Foundation who signed an MOU in 2016 to provide \$50 million to support VA research on prostate cancer. This helped catalyze precision oncology as a System of Excellence in 2019, allowing a network of VA medical centers to coordinate data in order to help affect veterans' lives.

Funding has allowed for 10 Precision Oncology sites across the VA (with the hope of six to eight more in the near future) operating in a hubcap like fashion with a center of expertise providing support to other sites. These sites allow for the possibility of contacting veterans and letting them know they are eligible for precision oncology care.

Research on metastatic prostate cancer has shown that genetic reappearing alterations makes up 20 percent of cases, metastatic instability makes up 5 percent, and CDK 12 alternations in 7 percent. This leaves close to 70 percent of cases where treatment is still unknown, though investigators are working on making in-roads into that.

Other highlights discussed:

- Three major clinical trials have been funded by ORD in the network and another 43 clinical trials opened through industry efforts.
- A biomarker driven basket trial, Prostate Cancer Analysis for Therapy Choice (PATCH), has been started through NCI.
- Act of Veterans, a collaboration between various research organizations, industry and NAVREF, is working on a way to streamline the process of opening high quality industry-sponsored clinical trials.
- Leveraging partnership with NCI NAVIGATE to increase the number of industry-sponsored trials.
- Working with National Oncology Program Office to bring trials directly to veterans, which is allowing an opportunity for tele-oncology.
- New therapeutics and diagnostics are being incorporated into the research portfolio.
- A new mechanism approach to increase genetic council capacity, being lead by Dr. Montgomery, is being piloted out of Seattle.
- Ongoing work using artificial intelligence to try to identify predictive markers of disease and therapeutic response and resistance.

Discussion and Q/A

Discussion included whether women-specific issues are being looked at by Precision Oncology (when one goes in for sequencing all cancers are sequenced at the same time, including those effecting women; and ORD is establishing a women's cancer initiative); whether cascade screening and testing is being used (something that will be looked at in the future); whether there are any plans to include nursing in the universe of precision medicine (discussions have been started).

Action Items discussed: Loop Catherine Wicklund into the subcommittee, Steve Dubinett will identify lung groups, and a meeting will be setup with ASCO to brief them on plans. Dr. Lee plans to speak with an ovarian cancer group.

Dr. Larry Mole, Chief Consultant of VHA Population Health, Research on Coronavirus and Q/A

Dr. Mole discussed the strategic response policy to COVID-19 put out by the Office of Emergency Management through the Population Health Office, which includes self-isolating if one or one's member of the family is sick, and to reduce close contact with members of the community and at work.

Dr. Mole made parallels between the 1917 flu and COVID-19, giving a concrete example of high mortality rates in New York City (frontline to the pandemic) compared to St. Louis, which was able to prepare and plan for it in advance and ultimately was able to blunt the impact of the pandemic through measures like social distancing.

Four-phase approach includes planning and responding: mitigate the impact on veterans, employees, visitors, and health care delivery systems by shifting priorities, resources, and standards of care; deciding where to deliver care: telehealth, inpatient care via zoning hospitals for standard care versus COVID care, outpatient care, and alternative sites such as field hospitals; classic emergency management preparedness: supplies, proper staffing, triaging via phone to mitigate an overabundance of arrivals at medical centers; and sustainment and recovery: continue providing care in whatever degree possible for as long as needed by taking measures such as rotating and resting staff and keeping sufficient supplies on hand.

Discussion and Q/A

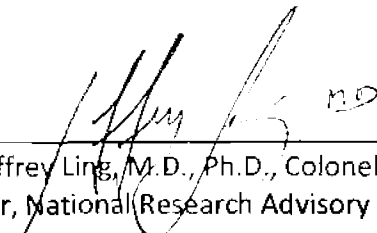
Committee discussion included embedding researchers in teams and as participants in group meetings, whether VA should conduct a point-of-care diagnostics study (supported as long as it doesn't disrupt the workflow), whether the committee should recommend ORD set guidelines and standards to aid in local R&D committees to approve research protocols, whether research elements should be embedded in the standard playbook for pandemics and to use this outbreak as a research opportunity to prepare for future pandemics; further, whether that should become a DoD/VA guideline in the same vein as a clinical practice guideline for emergency preparedness.

Public Comment

No members of the public wished to comment.

The meeting was adjourned at 3:00 p.m.

Submitted,



Geoffrey Ling, M.D., Ph.D., Colonel, US Army (retired)
Chair, National Research Advisory Council

**Department of Veterans Affairs
National Research Advisory Council (NRAC) Meeting
Room 104, 1100 First Street NE, Washington, DC
March 6, 2019**

Minutes

Members Present

Young, David, Chair
Bistoi, Lemanuel Lee
Farmer, Carrie M.
Guccione, Andrew A.
Lee, Jerry S. H. (via telephone)
Lillard, James W.
Lushniak, Boris (via telephone)
Maddox, Yvonne T.
Wicklund, Catherine A. L.

Present

Clancy, Carolyn, Deputy Under Secretary for Health for Discovery, Education and Affiliated Networks (DEAN)
Alterovitz, Gil
Atkins, David
Bever, Christopher
DePalma, Ralph (via telephone)
Dorn, Patricia
Duval, John – National Academic Affiliations Council Chair
Gleason, Theresa
Grunfeld, Carl (via telephone)
Huang, Grant – Alternate DFO
Kilbourne, Amy
Klote, Molly
Myrie, Kenute
Ramoni, Rachel - CRADO
Robinson, Rashelle - DFO
Muralidhar, Suma (via telephone)
Tenhula, Wendy – Deputy CRADO

Members of the Public

Charalmbakis, Naomi, FASEB
Tran, Hawk, NAVREF

Call to Order/Opening Remarks – Rashelle Robinson, Designated Federal Officer (DFO); Grant Huang, Alternate Designated Federal Officer; Brig. Gen. David G. Young, Chairman; Rachel Ramoni, DMD, ScD, Chief Research and Development Officer

Dr. Young called the meeting to order at 9:04 a.m. Ms. Robinson provided opening remarks regarding the committee, its purpose and the process for public comments. The members and other attendees then introduced themselves. Dr. Ramoni highlighted the need for practical, research-driven improvements for VA which promote veteran's health and well-being. She invited open dialogue and summarized the meeting topics. She and Dr. Young both emphasized that the research done in VA will be beneficial to the rest of the world too and thanked the committee for its efforts.

NRAC Operational Plan and Future Topics

Drs. Young and Huang facilitated discussions regarding the Committee 2019 Operational Plan. In addition to ideas previously raised by members, NRAC discussed other suggestions. Topics put forth include:

- conditions of lab facilities and the interplay of the VA and academic labs
- creating a benchmark to define and quantify a success rate
- working toward the proliferation of data from the VA to other medical organizations

Discussions reflected past challenges and lessons particularly ones surrounding governance/approvals and collection and sharing of data with other health related organizations. Other Office of Research and Development (ORD) staff also discussed the Foundations for Evidence-Based Policymaking Act as a key factor to consider regarding the need for open data.

Other topics raised included the transition to Cerner as VA's electronic health record. Questions on its implementation and ensuring data availability/use and their impact on research were raised. Comments were raised to prioritize making both new and old data accessible and applicable to the provision and improvement of care within VA. One member commented on the potential need for how clinical trial data and the real world evidence framework may potentially help with US Food and Drug Administration activities and/or safety related to medications.

Another suggestion focused on the importance of psychosocial care, including where people are from and where they are currently, psychosocially; how care impacts them; how a lack of care, decision-making, and behavioral change affect or are affected by the collection of big data. These are topics which are not well represented by any data collection agency. Digital health will likely be a key topic moving forward.

Further investigation into homeopathic and alternative medicines as supplements to the pharmaceuticals was also encouraged. It was noted that there are a variety of non-medical factors that have a role in the overall, holistic health of an individual.

The VA workforce, particularly, the recruitment and aging of VA investigators was raised as another future topic. Mr. Duval reported that the National Academic Advisory Council has begun to examine "workforce vibrancy," or the demographics of the existing and developing workforces in the VA. There may be opportunities to consider models and lessons being applied in other contexts. The recruitment

of bioinformaticians was also raised as a particular group worth considering because of their role in disseminating information to stakeholders.

Dr. Huang will organize the notes and requested that any other inquiries or suggestions be sent to him directly.

ORD Priority Goal #2: Increasing Real-World Impact of Research -- Dr. Kilbourne

Dr. Kilbourne presented a summary of activities from the Research to Real World (R2R) workgroup. The main goals, barriers, gaps and suggested directions were discussed to help with changes in processes and governance to ensure that innovations generated from research are aligned with VA national priorities and translated into practice more readily. As referenced previously, the Foundations for Evidence-Based Policymaking Act will also need to be considered and represents an opportunity for ORD. In particular it was suggested that ORD be provided with a voice at such discussions within VHA to ensure that research contributions would be known and considered in any policymaking activities. Other key recommendations for R2R activities included: 1) ensure a more consistent process by which research informs national priorities; 2) rapidly respond to requests from VA leadership to conduct research evaluation; 3) implementation of VA national priorities. The Committee did not raise any objections and supported the general direction for these efforts.

Remarks from the Deputy Under Secretary for Health for DEAN -- Dr. Clancy

Dr. Clancy joined the discussions and thanked the committee for its service and efforts. She noted that role of VA in training and research and described key directions for the 10X organization for which she is responsible. An important goal for VA should center on improving communications with other healthcare providers about the contributions VA research has made for national healthcare and medicine. Her role will be to help groups within VA to communicate better in order to optimize resources and minimize redundant efforts. She further stated, in response to a question from the Chair, that efforts to collaborate with the NAAC are just that, and not an attempt to combine the councils.

ORD Priority #1 – Enhancing Veteran Access to Clinical Trials -- Dr. Huang

Dr. Huang presented on progress related to this ORD priority that had occurred since the previous meeting. Efforts have focused on facilitating partnerships with industry or other federal sponsors of clinical trials to provide more opportunities to Veterans and VA clinical investigators to participate in these important studies. NRAC was thanked for its support of a subcommittee to specifically look into efforts related to industry partnerships which has been labelled Access to Clinical Trials (ACT) for Veterans. Activities will be focused on creating more efficient processes for such efforts including developing a model for a central/single point of contact, communicating assets and requirements to more effectively have partnerships, mapping workflows and key processes and enabling a single IRB review process for multi-site clinical trials. Future activities in this area are expected to refine specific activities and ideas for NRAC to consider. NRAC was supportive of activities overall and looked forward to future opportunities to comment on plans related to the subcommittee and the effort overall.

ORD Priority #3 – VA Data as a National Resource -- Dr. Alterovitz

Dr. Alterovitz presented on behalf of the team being led by Dr. Scott Duvall. The main update centered on activities related to establishing a VA data commons for storing and enabling access to VA data. Further descriptions were provided regarding steps for these activities and updates are planned for future NRAC meetings.

Precision Oncology -- Dr. Myrie

Dr. Myrie summarized a recent initiative involving ORD to enhance Precision Oncology efforts within the VA healthcare system. Information was presented on key elements of such a program: genomic testing and counseling; standardized care that matches leading medical centers; dashboards to monitor care; involvement in molecular tumor boards to discuss difficult cases; working to reach as many veterans as possible. Activities were planned to coordinate and possibly be augmented by the Prostate Cancer Foundation. Presently, there is a planned model to establish Centers for Excellence which would become “hubs” for networks for research and clinical activities at selected sites.

Discussions centered on clinical and research challenges in addition to the need for genetic counseling. Several members expressed particular interest in various aspects of this initiative. Since efforts are still in the relatively early phases of development, more information will be forthcoming. NRAC indicated the importance of resourcing research activities and ensuring that efforts are well aligned with the clinical activities within VHA.

Single Institutional Review Board Requirements -- Dr. Klote

Dr. Klote was introduced as a relatively new ORD employee following a distinguished career in the Army. Her background and expertise from her military career would be important for helping VA move towards adopting new Common Rule requirements and implementation of policies and procedures surrounding the use of a single IRB for multi-site research. Dr. Klote presented her plan for VA to be a model of effectiveness, compliance, and efficiency for multi-site research. This will require a lot of change in policy, infrastructure, and education. Many of the critical factors for achieving goals involved human resources, information technology, and information security and privacy. Her discussion centered on improvements in these areas but also on the role and processes involving the Research and Development Committees, a policy maintained by ORD. Questions were raised on how efforts could be more efficient and effective. The Committee agreed that resources were an important element for success.

Information Technology and Research Update -- Dr. Grunfeld

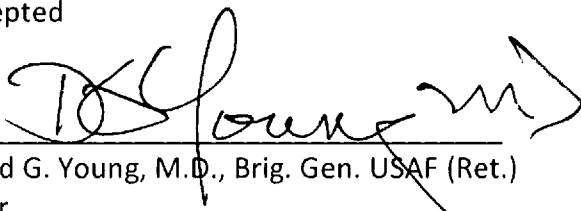
Dr. Grunfeld presented his work in chairing a committee commissioned by Dr. Ramoni focused on information technology (IT) requirements to support research. He indicated that a good working relationship with the Office of Information Technology has been established which had not been the case previously. Examples of needs, barriers and responses were provided as case studies. Movement toward cloud-based solutions was also discussed as a potential direction that VA research needed to have support for to continue successes. Policies (and policy changes) and budgetary/resource requirements are also being developed by the workgroup led by Dr. Grunfeld. These efforts would be critical to several of the other ORD initiatives presented to NRAC throughout the day. NRAC had previously expressed its support for IT changes/resources and were appreciative of this summary and

were encouraged to hear of these efforts. A follow-up action was for Dr. Huang to distribute Dr. Grunfeld's slides to the Committee.


Meeting Adjournment

No members of the public expressed any interest in providing comments. NRAC commented that they appreciated the new meeting format for enabling more dialog. Dr. Huang reminded everyone that the next meeting would be June 5 and requested that any questions or opportunities for improvement be sent to him. Dr. Young thanked members and adjourned the meeting at 3:03 p.m.

Accepted



David G. Young, M.D., Brig. Gen. USAF (Ret.)
Chair



**U.S. Department of Veteran Affairs
Office of Research and Development
Meeting of the National Research Advisory Council (NRAC)
June 3, 2020**

Minutes

Committee Members

Dr. Geoffrey Ling, Chairman
Dr. Sanjay Doddamani
Dr. Steven Dubinett
Dr. Carrie M. Farmer
Dr. James W. Lillard
Dr. Maria F. Lima
Dr. Ronald Poropatich
Dr. Ross McKinney
Catherine A. L. Wicklund, MS
Dr. Jerry S.H. Lee
Dr. Paula Schnurr
Matthew Kuntz, JD

Speakers

Dr. Grant Huang
Dr. Rachel Ramoni
Dr. Theresa Gleason
Dr. David Atkins
Dr. Wendy Tenhula

Marisue Cody, Designated Federal Officer
Rashelle Robinson, Alternate DFO

The virtual meeting of the VA's National Research Advisory Council took place on June 3, 2020. Designated Federal Officer Marisue Cody opened up the meeting with a couple of announcements, and performed a virtual roll call – 'attendees' are tuning in via the telephone, computer, or both.

Dr. Geoffrey Ling, Chairperson, welcomed the group, and noted the diverse makeup of the Council, as well as the veteran population that it serves. He spoke of his desire to get more veterans, and their families, involved in research – not just as subjects, but as young researchers/ investigators.

Dr. Lee spoke of the rising importance of convalescent plasma as an experimental treatment option for COVID-19 and other viruses. Plasma taken from the blood of those who have recovered from the virus is now in demand for possibly treating not only veterans, but the general population as well.

Dr. Huang put on a PowerPoint presentation detailing the COVID-19 research being done by the VA, and how the VA plans to collaborate with other agencies on the virus, as well as other subjects. The VA website known as ORD COVID-10 SharePoint (<https://dvagov.sharepoint.com/sites/vacovhacomm/admin/projects/covid19>) is loaded with relevant information for interested parties who have a VA e-mail address. The Office of Research and Development is heavily involved in so many other aspects of research as well – providing webinars, recruiting research volunteers, partnering with major medical centers nationwide, and so on.

There was a discussion regarding funding for both COVID-19 research and non-COVID. It was noted that infection rates for COVID are much higher amongst our African-American population.

Dr. Atkins spoke on the topic of mental health research, and the delivery of mental health services, and how both have obviously been affected by COVID-19. Dr. Gleason told the group about specific studies currently underway, or upcoming, including the research on the impact of COVID on healthcare workers, in and out of the VA.

Dr. Tenhula spoke of budget issues through fiscal year 2022. Of primary importance - the priorities of increasing the access of veterans to high-quality clinical trials, increasing the real-world impact of VA research, and putting VA data to work for veterans.

Precision oncology was added to the list of clinical priorities, which also includes suicide prevention, traumatic brain injury, PTSD, etc. Gulf War military exposures has been expanded to include the broader area of military exposures in general.

Dr. Tenhula reminded the group that budgeting, like most everything else, is a team sport, and she would love to get feedback from Council members, and other participants, on research funding issues.

Dr. Ramoni spoke about VISNs, and got some positive feedback from the group about possibly having a meeting with the 10N, the highest level of clinical partners. Chairman Ling reiterated his belief that top-notch clinical care has to be tied to research, and that the VA has truly been a step ahead of late, in the clinical research arena.

Action items:

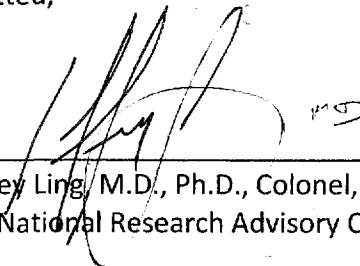
Establish a subcommittee on Diversity and Inclusion – Develop a concept paper for the next NRAC meeting for the full council to react to.

Follow up next meeting on the mental health portfolio focusing on disparities prevention and health care workers.

Follow up next meeting on how to work with our operations partners, to map out structurally how to build research as core to excellence in the health care system.

There was no public commentary, and DFO Cody announced that the next NRAC meeting will take place on September 2nd; virtual or face-to-face to be determined. The meeting was adjourned at 1:00 p.m.

Submitted,



Geoffrey Ling, M.D., Ph.D., Colonel, US Army (retired)
Chair, National Research Advisory Council

**U.S. Department of Veteran Affairs
Office of Research and Development
Meeting of the National Research Advisory Council (NRAC)
September 2, 2020**

Minutes

Committee Members

Dr. Geoffrey Ling, Chairman
Dr. Sanjay Doddamani
Dr. Steven Dubinett
Dr. Carrie M. Farmer
Matthew Kuntz, JD
Dr. Jerry S.H. Lee
Dr. James W. Lillard
Dr. Maria F. Lima
Dr. Ross McKinney
Dr. Ronald Poropatich
Dr. Paula Schnurr
Catherine A. Wicklund, MS

Speakers

Dr. Rachel Ramoni
Dr. Grant Huang
Dr. David Atkins
Dr. Theresa Gleason
Dr. Patricia Dorn
Dr. Wendy Tenhula
Dr. Donna Washington
Dr. Amy Kilbourne

Designated Federal Officers

Marisue Cody
Rashelle Robinson, Alternate

The virtual meeting of the VA's National Research Advisory Council (NRAC) took place on September 2nd, 2020. Designated Federal Officer Marisue Cody opened up the meeting with a couple of announcements and performed a virtual roll call – 'attendees' are tuning in via the telephone, computer, or both.

Dr. Geoffrey Ling, Chairperson, welcomed the group, and mentioned how pleased he was with the progress he felt was being made. He then handed it over to the first speaker Dr. Rachel Ramoni to give updates on the agenda and some COVID research activities.

Dr. Ramoni presented the agenda for the meeting with a brief description of the presenters and the topics. She then turned to talking about research in the Veteran's Health Administration (VHA) and how they can bring researchers together, with an emphasis on justice, equity, diversity, and inclusion. She suggests the solution is about building community through VA research, which includes investigators, veterans and VHA stakeholders.

The discussion that followed considered the VA's need to work with academia, its affiliated members, as well as private industry and both cultivate and build out its connections through big multi-institutional projects.

Dr. Ling presented the next topic on a work group on diversity and research and researchers and mentioned that the white paper had been constructed. The framework developed is about involving students as young as in middle school in VA-related research in an effort to increase the number of underrepresented groups in the field of medical research. Dr. Lee, Dr. Kuntz, Dr. Lima, Dr. Robinson quickly commented on their roles in the work group and their excitement for the project. Dr. Ling wanted Dr. Ramoni to approve the white paper so that they can submit it to the rest of NRAC for viewing and comments.

Dr. Atkins had his slides brought up and spoke about mental health impacts of COVID. By looking at a few different studies he and his team were about to assemble an analytic framework for thinking about the direct and indirect impacts COVID has on mental health and are gathering information on studies, the populations, interventions and outcomes. Directly of interest is how COVID and the pandemic have affected the VA's and other abilities to continue treating those with prior diagnosed mental health disorders, and what interventions are still effective. The hope is there will be some preparation for a possible resurgence and possible new lockdowns.

Dr. Washington then presented on the findings on racial and ethnic disparities in COVID-19 for VA users compared to the general population. The disparities exist in detection, infection, healthcare, and outcomes. The data shows that all racial-ethnic minority VA user groups had higher testing rates, infection rates, and hospitalization rates compared to non-Hispanic white veterans. With these data, the group is also looking to see how the VA compares with the US in terms of the outcomes among COVID-19 infected patients. The research is part of discovering what causes these disparities, such as obesity, and attempting to limit or treat them.

Dr. Kilbourne spoke about working with VA operations partners and how they can bridge the gap between research and operations so it's a more seamless process. She

mentioned some of the difficulties in these partnerships, such as timing and incentives, as well as some ways to bring the sides together, such as shared agenda's and goals, and getting veterans and other stakeholders involved in laying out priorities. She finished out by giving some examples of successful ORD-VA operations partnerships and what can be learned from them. Dr. Huang jumped in and spoke about how this has all become particularly important with COVID as research and trials need to move quickly, and steps they are taking to facilitate collaboration.

Dr. Ling ended the conversation and opened up for public comments of which there were none.

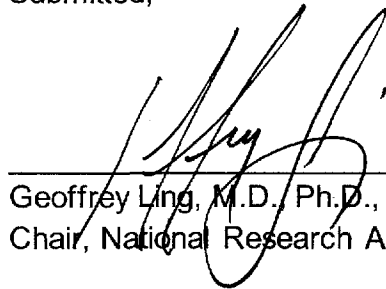
Action items:

Subcommittee on Diversity and Inclusion – Dr. Ramoni to review the concept paper on Diversity and Inclusion, share with full committee, and send forward to VHA leadership for review.

Establish a working group on alternative strategies for VA research – Dr. Poropatich to chair working group. Dr. Cody to assist in setting up meeting with interested members.

The meeting adjourned at 1:55 p.m.

Submitted,



Geoffrey Ling, M.D., Ph.D., Colonel, US Army (retired)
Chair, National Research Advisory Council

**U.S. Department of Veteran Affairs
Office of Research and Development
Meeting of the National Research Advisory Council (NRAC)
December 2, 2020**

Minutes

Committee Members

Dr. Geoffrey Ling, Chairman
Dr. Sanjay Doddamani
Dr. Steven Dubinett
Dr. Carrie M. Farmer
Matthew Kuntz, JD
Dr. Jerry S.H. Lee
Dr. James W. Lillard
Dr. Maria F. Lima
Dr. Ross McKinney
Dr. Ronald Poropatich
Dr. Paula Schnurr
Catherine A. Wicklund, MS

Speakers

Dr. Rachel Ramoni
Dr. Mark Roltsch
Dr. Cendrine Robinson

Attendees

Dr. Marisue Cody, DFO
Rashelle Robinson, Alternate DFO

The virtual meeting of the VA's National Research Advisory Council (NRAC) took place on December 2nd, 2020. Designated Federal Officer Marisue Cody opened up the meeting with a couple of announcements about the presentation materials and details on the public comment period. She then invited Dr. Geoffrey Ling, Chairman, to make opening comments.

Chairman Ling, called the meeting to order. He told everyone to stay safe in the current COVID environment and thanked them all for joining today's meeting. He then introduced Dr. Rachel Ramoni for the day's first presentation.

Dr. Ramoni presented on the highlights of what they have accomplished in the area of COVID. One of the things the VA ORD got feedback on handling really well was communication. She said they received feedback from the field that not only was the communication clear, but they were happy and impressed with what the ORD was actually accomplishing with the COVID Response Team, and Dr. Ramoni credited the VA with acting as a complete enterprise rather than as individual teams with these

successes. Another highlight she mentioned was the VA ORD working on its infrastructure and realigning its organization to accommodate and accomplish even more, such as the first biorepository. She then spoke about additional accomplishments such as Operation Warp Speed, the dedicated enrollment sites for Million Veteran Program, and remaining focused on addressing the diversity, equity, and inclusion during COVID amongst others.

She felt the VA was a tremendous asset to the country especially now as it plays a role in bringing other agencies together to collaborate on research and response regarding COVID. Dr. Ramoni last mentioned the VA's attempt to reach a gold standard on analysis and desire to bring people together to work on similar studies and streamlining what they can accomplish as a whole. Some discussion followed and Dr. Ramoni spoke about some items she feels are worth pursuing such as bringing researchers together who are working on similar studies. A few members also spoke about the process of sharing data outside the VA and the drawbacks and advantages of that.

Dr. Ling then introduced the next meeting section which was a discussion on the DEI White Paper that had been reviewed and commented on by a subcommittee. The main points brought up were that the paper as written had done a good job of being concrete in how to put these new plans into operation, but there was some agreement that perhaps it was a bit too specific with no room for flexibility. There was some discussion on how quickly the program could be ramped up, and perhaps hire outside contractors to help get everything set up more quickly. It was also discussed to look at other agencies with already active DEI programs and draw best practices from them since VA has unique access to the public through their health services. The next steps were to finalize the White Paper by next NRAC meeting and to start developing a budget to move the programs forward.

Dr. Robinson and Dr. Roltsch then presented on their work in promoting DEI within the VA ORD. They had received \$1 million to enact their plans and explained they had four main goals. First was to develop a diverse scientific workforce through training and funding opportunities. Second was to stimulate research on minority health and reducing health disparities. Third was to focus on promoting a culture of inclusion in their own workplace. And fourth was to ensure equity is promoted in all scientific activities including their scientific review process. Part of their process is improving the layout of the typical research career through workshops and training supplements for diverse populations to not only promote inclusive hiring but to ensure DEI growth at all seniority levels. They then spoke about some of the specific steps that have already been run as examples of how they are executing these goals, and some future steps they are planning.

A discussion followed that had other NRAC members making suggestions on projects they could try such as connecting students with researchers around the country utilizing digital technology to make that possible. Everyone was very supportive of the DEI work being done and is hopeful to see promising data behind the activities.

After a brief recess, Dr. Poropatich presented on the NRAC Subcommittee White Paper which is about an alternative strategy for VA research. The goal of the presentation is to have the paper reviewed by the NRAC for comments and feedback. The White Paper starts by explaining the main mission of VA research is to develop high quality clinical trials with real world impacts for veterans. It then spoke about strategies for improving this process including the idea of utilizing the triple helix, which involves utilizing industry, academia, and the government collaborations to ensure the best use of resources. They are hoping the White Paper can be successful in getting better funding in FY 22 for accomplishing this work either from congress, or externally from various sources. Part of that funding ask takes IT support into account so researchers can get access to the large amounts of Data Repositories out there that can supplement and inform future research.

Some discussion followed about possible use cases to apply these new strategies to. They also spoke about the use of OTA's. Dr. Poropatich mentioned and understood why the VA can't currently use them, but there are actions being taken to gain access. They also discussed success metrics and felt overall partnerships arranged, and funding brought in would be a good measurement, along with ultimately products and solutions brought to veterans through these strategies.

Dr. Ling started a discussion next on the NRAC annual report. Dr. Cody explained that after reading the report, they will need the members to both evaluate the NRAC in portfolio balance and program management and respond to a survey that asked about how the report was in general and if there are any suggestions to do the report differently next year. There was some discussion and agreement that the report was an excellent way of demonstrating the amount and quality of research that has gone on in the last year throughout the VA made even more impressive by the relatively small budget allocated.

Some critiques were given as well. Mentioned was having more information on the health care and policy impacts all of the research has had, and perhaps including an upfront executive summary that offers highlights of the full report. Some also suggested adding in some challenges the VA is facing and use the report to explain how much more could be accomplished with a larger budget.

Dr. Ling ended the discussion and opened the meeting up for public comment. Dr. Cunningham was the only person who spoke, and he thanked everyone for the DEI discussion and work being done. He felt very close to the issue as a scientist of color and wanted to offer his support for their work.

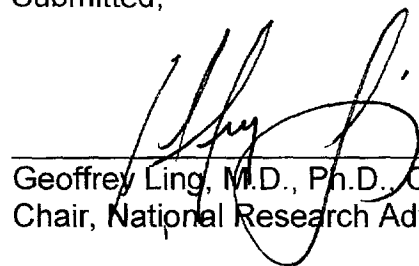
Dr. Cody finished up by informing everyone the next meeting would be March 3rd and follow a similar schedule to this year. Dr. Ramoni then quickly ran through the action items that came out of the meeting. Dr. Ling ended the meeting by telling everyone to stay safe and healthy through the holiday season.

Action items:

- Next meeting will discuss lessons learned, things we should continue doing.
- We want to get the RFI out for diversity, equity, and inclusion in February so that we can make an award in FY-21 and get some students in FY-22. Develop and submit recommendations about DEI to the Secretary.
- Along the lines of alternative strategies, get a couple of concepts together. It sounds like around cancer and around the Scott Hannon Act. Paula and Matt and others volunteered to begin with scoping the response to the Scott Hannon Act.
- Create an executive summary of NRAC report with something punchy for the transition team.

The meeting adjourned at 1:50 p.m.

Submitted,

A handwritten signature in black ink, appearing to read 'Geoffrey Ling', is written over a horizontal line.

Geoffrey Ling, M.D., Ph.D., Colonel, US Army (retired)
Chair, National Research Advisory Council