

**U.S. Department of Veteran Affairs
Office of Research and Development
Quarterly Meeting of the National Research Advisory Council (NRAC)
December 7, 2022**

Minutes

Committee Members Present

Dr. Ronald Poropatich, Chairman
Matthew Kuntz, JD
Dr. Paula Schnurr
Dr. Melina Kibbe
Dr. Dallas Hack
Dr. Cato Laurencin
Dr. Julie Tomaska
Thomas Zampieri, PA
Dr. Rajeev Ramchand

Committee Members Excused

Dr. Sanjay Doddamani
Dr. Steven Dubinett

Speakers/Presenters

Dr. Carolyn Clancy
Dr. Joseph Constans
Dr. Molly Klote
Dr. Rachel Ramoni
Dr. George Lathrop
Dr. Robert O'Brien

Attendees

Rashelle Robinson, Alternate DFO
Lakeisha Skinner, Consultant/Note-Taker

Attendees Excused

Liza Catucci, DFO

The virtual meeting of the VA's National Research Advisory Council (NRAC) took place on December 7, 2022. Dr. Ron Poropatich opened the meeting with announcements about the presentation materials and details regarding the public comment period. He invited Dr. Rachel

Ramoni, Chief Research and Development Officer (CRADO), to briefly reiterate the goals and accomplishments of the NRAC. He then invited Dr. Wendy Tenhula, Deputy CRADO, to share updates on the meeting's agenda.

Dr. Poropatich called the meeting to order. He opened the floor by taking attendance of committee members, outlining the purpose of the NRAC as described in the charter, reviewing key takeaways from the previous NRAC Meeting, and describing the NRAC activities since the last quarterly meeting held in September 2022.

Dr. Poropatich announced that the NRAC will select a new member due to Dr. Sidney Hinds's resignation from the committee. Dr. Tenhula said that the NRAC hopes to formally appoint Dr. Kent Kester as the new committee member to replace Dr. Hinds in time for the next NRAC Quarterly meeting. Dr. Poropatich shared Dr. Kester's background and areas of expertise.

Dr. Poropatich inquired if anyone else had comments to share before the NRAC proceeded with the agenda. Dr. Ramoni highlighted the existence of the NRAC in a dynamic environment and described new items of concern that came forward during the week prior to the meeting. Dr. Ramoni stated that **the ability to keep our H1B and J visa holders in research** is an ongoing concern and a threat to many projects and research personnel across the country. That is because the visa holders fill positions that are difficult to fill with U.S. citizens or permanent residents. She said some relief may be found within VA policy itself, but the appetite for VA to address it is currently unclear. Dr. Ramoni commented that multiple sites reached out to the Office of Research and Development (ORD) with concerns. Many H1B visa holders have been placed into without compensation (WOC) appointments, which Dr. Ramoni stated may not be legally viable due to requirements of the H1B visa. In the past, individuals with H1B visas were placed on Intergovernmental Personnel Agreements (IPAs) which is another vehicle for hiring employees. However, at present VA policy precludes use of that vehicle for individuals with H1B visas. Thus, there is no straightforward path to retain the visa holders within VA. Dr. Ramoni stated that ORD is working closely with the VA Office of General Counsel (OGC) and Workforce Management and Consultation (WMC) to address the issue. A more flexible policy regarding IPAs would benefit the agency while remaining within the law.

Dr. Poropatich concurred that the Visa holders' issue is worrisome and inquired about data regarding the number of those affected. Dr. Ramoni responded that ORD is conducting a survey on this out of Boston, which to date estimates that at least fourteen individuals and their research projects are affected. Individuals may be tied to multiple research projects, and those projects would have to stop abruptly if we are unable to retain the visa holders assigned to those projects. Dr. Ramoni stated that Tony Laracuate, ORD Director of Field Operations, has been instrumental in responding to the visa holder issue and the criminal conflict of interest issue in 18 U.S.C. section 209, which is pending legislative resolution.

Mr. Matthew Kuntz inquired whether VA lawyers, or external lawyers provided the legal rulings. Dr. Ramoni responded that section 18 U.S.C. § 209 came from the Department of Justice and requires legislation to resolve. The H1B visa and WOC appointment components currently

remain in the balance in the Senate and are external to VA. Dr. Ramoni said that the VA has some latitude in terms of interpretation regarding the IPAs.

Dr. Poropatich thanked Dr. Ramoni for bringing the issue to the NRAC's attention, stated that they may engage in more discussion if time permits today, and requested that Rashelle Robinson add it to the next agenda if it is an issue that the NRAC may be able to impact.

Dr. Poropatich invited Dr. Carolyn Clancy, Assistant Undersecretary for Health (AUSH), for Discovery, Education and Affiliate Networks (DEAN) to provide **AUSH and DEAN Remarks**. Dr. Clancy thanked everyone for joining the meeting and expressed her admiration for the positive impact the NRAC has had over the years on the VA and Veterans. Dr. Clancy addressed Dr. Ramoni's concerns about the H1B visa status issue and informed the group that DEAN is working with the Chief Medical Officer in her network to plan next steps for a potential solution. Dr. Clancy stated that she will keep the NRAC informed on actions.

Dr. Clancy also thanked Dr. Poropatich for his leadership this year with the NRAC and support of several subcommittees. Dr. Clancy mentioned Dr. Shereef Elnahal's return to the VA as the new Under Secretary for Health (USH), summarized his background, and stated that he is a strong advocate for VA research. Dr. Clancy outlined the following six priorities that Dr. Elnahal has identified for VHA: Supporting Veterans with military environmental exposures consistent with the Promising to Address Comprehensive Toxics (PACT) Act; Improving and expanding access to care; Accelerating VA's journey to a High Reliability Organization; Promoting Veterans Whole Health; Preventing Veteran Suicide; and hiring faster and more competitively.

Dr. Clancy credits Dr. Elnahal and Secretary McDonough for their expertise and negotiations with the Hill for expanded authorities in the PACT Act. She announced that the House of Representatives passed the VA Infrastructure Powers Exceptional Research (VIPER) Act which was sent to the Senate in November. Dr. Clancy emphasized the importance of Congress passing a final appropriations bill for Fiscal Year (FY) 2023. She also mentioned that she looks forward to a higher level of integration between VA research and clinical care in FY 2023.

Dr. Clancy noted that ORD, with Dr. Ramoni leading the charge, is embarking on a major enterprise transformation initiative to change how it conducts business to better integrate its operations into the VHA enterprise. Dr. Clancy indicated the target audience for this initiative includes VA operational leaders and frontline clinicians. She strongly believes that Dr. Ramoni will excel in spearheading this initiative and its impact on the nation's largest integrated healthcare system. Dr. Clancy emphasized the importance of supporting and conducting research which has meaningful impacts on Veterans' lives. Support for translating research into meaningful impacts will require collaboration and the enterprise transformation initiative aims to build processes and systems that facilitate and embed collaboration between ORD, VA program offices and clinical partners in day-to-day operations. Dr. Clancy stressed the importance of beginning these collaborative efforts early and appreciates receiving feedback from end users as necessary to ensure the successful translation of research into practice. Early collaborations will benefit Veterans and the global population. Dr. Clancy stated that the integration of VA research

into the larger VA enterprise is crucial and will increase visibility into VA research and VA research needs to support clinicians in areas that are most relevant to them for improving current and future care.

Dr. Clancy mentioned that guidance about VA in-person meetings continues to evolve and stated that she will keep the NRAC informed as decisions are made regarding the possibility of the NRAC returning to in-person or hybrid meetings. Dr. Clancy closed by thanking the NRAC for their time and dedication to VA.

Dr. Poropatich invited Dr. Joseph Constans, VA ORD Senior Program Manager for Suicide Prevention in Clinical Science Research & Development (CSR&D), to lead the second presentation, an **Overview of VA Funded Research on Suicide Prevention Research**. Dr. Constans stated that VA ORD funding for suicide prevention was just over \$18 million for FY2022. Most of the funding was applied to HSR&D and CSR&D. Dr. Constans built on Dr. Clancy's previous comments about collaboration and discussed the importance of operational partners. The primary operational partner for ORD suicide prevention work is the Office of Mental Health and Suicide Prevention (OMHSP), which establishes policies and strategic plans for suicide prevention. OMHSP is responsible for our surveillance program, the Veterans' crisis line, and supporting small operational projects that are not necessarily deemed as research by an IRB, but which generate new information and knowledge. OMHSP also supports two research centers in the field: The Rocky Mountain MIRECC (Mental Illness Research Educational Research Clinical Center) and the Canandaigua Center for Excellence for Suicide Prevention, Canandaigua, NY. Dr. Constans stated that ORD's role in Suicide Prevention is to establish the evidence base for practice and ORD funds primarily investigator-initiated research. ORD also establishes research priorities and issues Requests for Applications (RFAs) and works to bring research into practice. Specificity of the RFA's might increase depending on the needs of OMHSP. Dr. Constans also outlined two ORD Research Centers: The Suicide Prevention Research Impact Network (SPRINT) and the new Center for Harmonizing and Improving Interventions to Prevent Suicide (CHIPS).

Dr. Constans emphasized the importance of differentiating between Veteran and non-Veteran suicide deaths. The OMHSP oversees surveillance and coordinates with the DoD Defense Manpower team to compile a list of identifiers for known veterans. These identifiers are then sent to the Centers for Disease Control and Prevention (CDC) to be used for possible matching with death certificates. CDC returns the death certificates believed to match this data to VA OMHSP and VA uses its own algorithm to further enhance the accuracy of the data. The program is used to accurately track data despite the controversy surrounding it. Data indicate that 343 fewer Veteran suicides occurred in 2020 compared to 2019. Despite the decrease in Veteran suicide deaths, disparities remain between Veterans and non-Veterans. According to the data Dr. Constans presented, death by firearms is the leading cause of suicide among Veterans, with 7 out of 10 using firearms for suicide. Dr. Constans summarized that suicide rates among the 18 to 35 age cohort increased from 2019-2020 while rates for all other age groups decreased. 60% of Veteran suicide deaths are occurring in Veterans who are not actively receiving VA services. Two documents guide VA suicide prevention efforts: The White House's 2021

Reducing Military and Veteran Suicide and the VA's 2018 National Strategy for Preventing Veteran Suicide. Dr. Constans said that ORD's role is to help support and develop the evidence base for these strategies and use this information combined with our health care infrastructure to improve our suicide prevention efforts. Dr. Constans outlined ORD's six priority areas and highlighted some of their accomplishments and ongoing plans; 1) Lethal Means Safety, 2) Suicide Prevention in non-VA Veteran community and in transitioning service members, 3) Improving Risk Identification, 4) Developing Interventions and matching to risk factors, 5) Address upstream risk and protective factors, and 6) Coordinate research and share data. These priority areas match closely to disparities identified between Veterans and non-veterans who died by suicide including the use of firearms as a means of suicide, the number of Veterans who died by suicide who are not receiving VA services, and the number of young veterans ages 18-34.

Dr. Poropatich opened the floor for NRAC members to ask Dr. Constans questions about his presentation. Dr. Ramchand asked Dr. Constans if efforts are underway to include suicidal or suicidal behaviors as components of their studies. Dr. Constans responded that there are efforts to embed those measures into studies regarding chronic pain treatment. However, those efforts are driven mostly by investigators rather than a top-down recommendation as Dr. Ramchand suggested. Dr. Constans also stated that one of our missions in developing this infrastructure is to create recommendations on common data elements that may be used across studies including studies that don't specifically focus on suicidality to enable us to study upstream factors that may not or may be hard to identify.

Dr. Molly Klote, the Deputy CRADO for Policy, Protection, and Education (PPE) provided the third presentation entitled **Advances in Enterprise Support with a Highlight on the NRAC Diversity and Inclusion Subcommittee**. Dr. Klote reviewed the enterprise infrastructure support that was created through ORD funding, and how enterprise support enables research and compliance as well as oversight of ORD management. Dr. Klote discussed the efforts made by the NRAC Diversity, Equity and Inclusion (DE&I) Subcommittee and how it has positively affected the VA since its establishment. She stated that efforts to create a common enterprise infrastructure enable researchers to be more compliant with policies, address regulatory issues that arise, and lowers hurdles for them so that people can do their work. Dr. Klote emphasized the importance of viewing the entire spectrum of VA research to ensure that when we make decisions where to invest our research dollars, we have a comprehensive view. She provided an overview of tools, committees, programs, contracts, and information flows and interactions between them. Highlights included: dashboards that centralize data, educational support tools including the Research Law Explorer (searchable list), VA Innovation and Research Review System (VAIRRS), VA Electronic Determination Aid (VAEDA), a first of its kind with a Field Inquiry Navigational Database Pro (FIND Pro) tool where all policies and FAQs are included in a searchable format. For operational support, a Partnered Research Program (PRP) Office was established to improve access to clinical trials for VA's industry partners. The PRP is in high demand, and current efforts are underway to increase staffing and centralization.

Dr. Klote said the NRAC DE&I Subcommittee, comprised of twelve different groups, was established in 2020 to help review DE&I materials and messaging being sent to underserved veterans to encourage them to enter our COVID trials.

The fourth presentation “**Research Enterprise Transformation Update and Overview**” was led by Dr. Rachel Ramoni, CRADO. Dr. Ramoni stated that the goal of the Enterprise to take an old system and transform it into an integrated system. She highlighted the following achievements of the Research Enterprise Transformation initiative: **organizational realignment** which is being reshaped into six units (and 25 sub-units) reporting directly to Dr. Ramoni; **Actively Managed Portfolios (AMPs)** – the Precision Oncology AMP was launched earlier this month; **conducted an initial assessment of IT software and systems** that will inform an IT and Data Governance strategic plan in FY2023; provided **financial process guidance to the field**; slated a series of **professional development** courses to begin in 2023; finalized plans for transitioning full time employees in the field to **Central Research HR** staff in early 2023; **Field Enterprise Research Support Service (FERSS) pilot** that provided 14 sites with access to short-term contracting resources; and a **Partnered Research Program** increased engagement with external partners. Dr. Ramoni also previewed Enterprise Transformation Activities to occur in FY 2023.

Dr. Poropatich opened the floor for NRAC members to ask Dr. Ramoni questions. The group did not have questions or comments.

The fifth presentation, “**Updates on VA Sensitive Species Research Initiatives – the Five-Year Plan**” was led by Dr. George Lathrop, Chief Veterinary Medical Officer. He reviewed and noted a dramatic decline in the use of sensitive species in VA research between 2004 and 2021. Dr. Lathrop noted that we have nine current studies still in some phase of active protocol work or in the publishing phase.

Dr. Lathrop noted that the subcommittee established a new and Enhanced Review Process (ERP) that has proven to work well. Dr. Lathrop also noted that they are developing education and mentoring to enable investigators and scientific program managers to anticipate what to expect when conducting research using sensitive species. The Sensitive Species Executive Committee is meeting the week of December 12 to vote on a game plan and begin executing it.

He noted that three protocols for sensitive species were submitted and reviewed in 2021-2022. Two were reviewed but did not meet newly established criteria, and one was forwarded for Secretary approval. Dr. Lathrop also announced the VA’s success in soliciting projects for 2022 with eighteen LOIs in the process of being reviewed for 2023. This should result in 7-8 proposals. Lastly, he stated that establishment of the Independent Review Panel, which is mandated by law, was the most successful project of the subcommittee. After putting out an RFA that received zero proposals, Dr. Lathrop approached individual companies interested in this type of work to negotiate proposals. A contract was ultimately awarded to a scientific consulting firm.

The final presentation, “**Overview of VA Homelessness Research**” was led by Dr. Robert O’Brien, Scientific Program Manager, Mental and Behavioral Health, HSR&D. Dr. O’Brien noted the intersection of work between the VA Homelessness Office, and Veteran Justice

Involvement Office and the high risk for homelessness among Veterans exiting the justice system. Dr. O'Brien provided the following statistics on Veterans' homelessness from Department of Housing and Urban Development (HUD) data: on a single night in January 2022, 33,136 Veterans were experiencing homelessness, down from 37,252 in 2020 or a 55.3% reduction in Veterans experiencing homelessness since 2010. Dr. O'Brien stated VA's influence on the important and effective "housing first" model of intervention which provides housing before providing supportive services for mental health concerns and substance abuse issues. He also presented recent HUD 2022 findings on Veterans' homelessness, showing that the average age of sheltered Veterans was younger, which implies that more work needs to be done during the transition phase from the military to civilian life.

Dr. O'Brien also noted statistics regarding racial and ethnic disparities represented in the sheltered veteran population. He stated that the VA's National Center on Homelessness Among Veterans (NCHAV) uses ORD research to inform annual strategic planning in the Homeless Programs Office (HPO). Dr. O'Brien said HSR&D supports collaboration between the Homeless Office and the Justice Involvement Office for studies on psychosocial transition and veterans with mental illness or substance abuse disorders as they leave prison. Dr. O'Brien outlined additional collaborations on studies of veteran homelessness including the Study to Assess Risk and Resilience in Servicemembers (STARRS), and the VA Homelessness Integrated Process Team (VA-IPT) which is a VA-wide advisory team assisting senior leaders with developing evidence-based policymaking principles, disseminating them, and advising on implementation as they relate to preventing and ending veteran homelessness.

Dr. O'Brien mentioned the next generation of Veterans Homelessness researchers, who recently received Career Development Awards (CDAs). They include Dr. Sonya Gabrielian, MD; Dr. Audrey Jones, Ph.D.; and Derek Novachek, Ph.D.

In closing, Dr. O'Brien summarized the research goals, study challenges, and dissemination challenges that lie ahead in the area of Veterans' Homelessness Research.

Dr. Poropatich opened the floor for questions. Dr. Laurencin asked Dr. O'Brien how his research has made material changes in numbers of homeless, their health, and effects on suicide rates. In response, Dr. O'Brien indicated he will work with the National Center to gather information and data and report back to the NRAC. Dr. David Atkins also inquired what our current research is doing to further refine models of care so that we can continue to decrease numbers of veterans experiencing homelessness. [**Action:** Dr. O'Brien to gather data and report back]

Public Comments:

Dr. Poropatich invited public comments. Neither the public nor members of the NRAC had comments or questions to share.

Dr. Poropatich and Dr. Ramoni concluded the meeting.

Next Meeting:

The next meeting of the NRAC will be held on March 1, 2023, from 11 a.m. to 2 p.m. EST. Ms. Robinson reminded the invitees that the NRAC meets quarterly on the first Wednesday of the month beginning in March of each calendar year.

Action Items:

- Dr. Clancy will reach out to Dr. Ramoni about possible solutions to challenges the VA is facing with the H1B/Visa holders' issue.
 - ORD will provide an update on the impact to the system of the H1B Visa and WOC issue (i.e., how many across the VA are affected?) and what the NRAC can do to assist.
- Dr. O'Brien will gather data and report back to the NRAC on the impacts of our current research on the number of Veterans experiencing homelessness.
- Dr. Constans will report on whether there has been a downward trend in suicide by veterans with prior VA contact versus veterans with no VA contact.
- ORD will provide a legislative update to include status of Section 209, VIPER Act, PACT Act, etc.

Adjournment:

The meeting was adjourned at 1:49 p.m. ET.

Submitted,

DocuSigned by:
Ronald Poropatich
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Dr. Ronald Poropatich
Chair, National Research Advisory Council

