U.S. Department of Veterans Affairs
Office of Research and Development
Quarterly Meeting of the National Research Advisory Council (NRAC)
October 11, 2023

Minutes

Committee Members Present
Dr. Ronald Poropatich, Chairman
Dr. Steven Dubinett
Dr. Melinda Kibbe
Matthew Kuntz, JD
Dr. Cato Laurencin
Dr. Rajeev Ramchand
Dr. Paula Schnurr
Dr. Julie Tomaska
Thomas Zampieri, PA

Committee Members Excused
Dr. Dallas Hack
Dr. Sanjay Doddamani

Speakers/Presenters
Dr. Rachel Ramoni
Dr. Wendy Tenhula
Dr. Christopher Bever
Dr. Stuart Hoffman
Dr. LaTonya Small
Dr. Holly Krull

Attendees
Liza Catucci, DFO
Dr. Allison Williams, Alternate DFO
Rashelle Robinson, Alternate DFO
Kristan Buotte, Contractor/Note-Taker

The virtual meeting of VA's National Research Advisory Council (NRAC) took place on October 11, 2023. The meeting began following a FACA 101 Training provided to the NRAC by LaTonya Small, Program Specialist, ACMO. Dr Ronald Poropatich, NRAC Chairman, officially called the meeting to order at 11:30 a.m. ET.

Dr. Poropatich introduced the upcoming discussions, which included agenda review. Dr. Poropatich discussed new member nominations. Four NRAC member openings will become available on April 1, 2024 following expiration of second terms for four active members. Ms.

Liza Catucci, the Designated Federal Officer (DFO), elaborated on the process to formally nominate individuals for membership.

Ms. Catucci confirmed the next NRAC meeting will be held virtually on December 6th from11a.m. to 2 p.m. EST. She indicated that ORD is considering holding the March 2024 meeting as in-person at VA's ORD Office at 811 Vermont Ave in Washington, DC. Ms. Catucci confirmed that all NRAC members' appointments will remain active through the end of March 2024. This will enable all members to attend upcoming meetings in December 2023 and March 2024. Among the eleven current members, four are in their second term and will not be able to be re-appointed as of April 1st, 2024. They are Matthew Kuntz, JD, Dr. Paula Schnurr, Dr. Sanjay Doddamani and Dr. Steven Dubinett. All other members can be reappointed for one more two-year term. Anyone who is interested in nominating a new member can do so by emailing the individual's information to the incoming DFO, Dr. Allison Williams. A description of the criteria the NRAC requires for nominees is included in the meeting material attachments. This includes expertise in particular areas of science as well as individuals who are Veterans who can speak on behalf of Veterans' needs.

Dr. Poropatich referenced Dr. Kent Kester, a potential nominee. Liza confirmed that Dr. Kester's application is in the final stages of approval and is with the Undersecretary's Office. They are hopeful that it will reach the Secretary for approval before the NRAC Meeting in December.

Dr. Poropatich turned the meeting over to Dr. Rachel Ramoni, Chief Research and Development Officer (CRADO) for welcoming remarks. Dr. Ramoni indicated that as part of the enterprise transformation ORD created a new position for a full-time dedicated FTE to provide NRAC administrative support. This effort has been championed internally by Ms. Catucci for some time. Dr. Ramoni deferred to Dr. Wendy Tenhula, Deputy CRADO, to discuss her items prior to Dr. Ramoni's presentation.

Dr. Tenhula introduced the incoming DFO, Dr. Allison Williams. Dr. Williams came to ORD at the end of July, 2023, as the Director of Operations, and as part of that role she will serve as the DFO for the NRAC. Dr. Williams has over 20 years of research experience, including program development, basic science, clinical and health services research. Most recently, she was the Associate Chief of Staff for Research (ACOS-R) at Bay Pines VA in Florida. She also has been advocating for additional support for the NRAC alongside Ms. Catucci. Dr. Tenhula gave a sincere thank you to Ms. Catucci for her efforts in support of the NRAC, in addition to her full-time position as the Deputy Director of Health Services Research. Dr. Tenhula returned the meeting to Dr. Poropatich to introduce the next presentation.

Dr. Poropatich gave the floor to Dr. Ramoni for the VA Enterprise Transformation update. She was joined by Dr. Christopher Bever, Deputy CRADO, Investigators, Scientific Review and Management (ISRM), and Dr. Stuart Hoffman, Senior Portfolio Manager.

Dr. Ramoni began by mentioning the 100 VA Medical Centers (VAMCs) that are independently conducting research. The primary roles of the Office of Research and Development (ORD) are centered around funding and policy. Dr. Ramoni would like the organization to function as "one VA". VA is a powerhouse, not only to what VA brings to the table, but also the academic affiliates. Dr. Ramoni discussed the need to rethink the role of Central Office and more closely align how Congress views the organization. Congress previously asked what VA research as whole is doing. VA is a large and complex system and has undertaken several efforts that are linked to one another. The organizational alignment is a reimagining of Central Office as a headquarters and ensuring they have staff members and colleagues to cover all functions both internally and as a headquarters. This includes having an individual who is dedicated to NRAC administrative support. The goal of the ISRM is to function as a more integrated group within itself across disciplines, as well as integration with clinical and other program office partners in VA.

The reorganization requires an update to ORD finance systems to improve funding tracking and increase insight into where funding is extended into the field. Training and community building efforts have taken place and Dr. Ramoni held over 25 listening sessions of various sizes across the country. The issues that people have been facing include the fragmenting of IT resources and the under resourcing for required work. Human Resources also challenging. Dr. Ramoni partnered with Workforce Management and Consultation (WMC) to set up a specialized research HR unit. In addition, they are experimenting with centralized contracting that multiple sites could tap into, rather than having individualized contracts. Central Office has been focusing on leadership development and initiated an employee training program called STEAM. Several deputies at every level of the organization as well as the head of finance now report to Dr. Ramoni.

Central Office undertook a review of all positions and their respective functions. A significant number of activities were found to be critical and should be at the forefront of efforts. The Office is also studying 59 ORD-funded centers, like those in Health Services and Rehabilitation Research, and analyzing their functions to uncover any duplication of efforts and determine opportunities for synergy under ISRM. Dr. Ramoni plans to meet with finance to outline the requirements received from Congress, and how to ensure the organization accounts for the appropriate funding for those requirements.

Dr. Ramoni described what is driving the integration with the clinical partners to include a review of the components of a Learning Health System. She indicated the first step of integration is an agreement to work together to determine problems. Other components include community building and structures and processes that enable stakeholders to act on their inherent motivations and become involved in the network. Dr. Ramoni explained how research generates new knowledge related to the network's clinical focus and knowledge related to improvement of the network itself. For example, lung cancer screening drives a significant amount of research in

the Lung Precision Oncology Program (LPOP). Data analytics ensures that there is no duplication of efforts.

Dr. Ramoni described the structure of LPOP, which includes the Executive Steering Committee, workgroups (e.g., Veteran Engagement) and Sub-workgroups like the Lung Cancer Screening (LCS) Scientific Radiomics and LCS Clinician and Scientific Outcomes. LPOP is an example of Actively Managed Portfolio (AMP) functionality currently in place. Dr. Ramoni presented a graphic display of the LPOP Nationwide Network, which includes hubs in every VISN and 79 spoke sites (and growing). To be considered active, all sites must be able to report on quality metrics. Sites participate in workgroups and offer Veterans enrollment in clinical trials and research. These sites receive both research and medical care funding. This is a prototype of how Dr. Ramoni would like to work with the clinical side of the house.

Dr. Ramoni concluded her portion of the presentation and turned the discussion over to Dr. Bever to present on ISRM. Dr. Bever discussed the transition of the services to broad portfolios of Veteran need. He displayed the current/traditional situation in the Office of Research and Development (ORD), consisting of the four services of research disciplines: Clinical Science Research and Development, Rehabilitation Research and Development, Health Services Research and Development, and Bio-medical Laboratory Research and Development. Historically, funding of research projects was done through these four services. A transition is currently ongoing to replace services with Actively Managed Portfolios (AMPs) and Broad Portfolios. In process thus far are the Precision Oncology AMP and the Pain/Opioid Use AMP. Upcoming are the Traumatic Brain Injury AMP, Suicide Prevention AMP, and Military Exposure AMP. Broad Portfolios are under development including the Health Systems Broad Portfolio, Brain, Behavioral, and Mental Health Broad Portfolio, Rehab Broad Portfolio, and Medical Health and Aging Broad Portfolio.

Each Broad Portfolio is established to support Veteran-centric research from the foundational to translational within a defined purview. Broad Portfolios include studies across the research spectrum (foundational investigations to point of care), and act as an incubator for research to go from concept to implementation. An AMP could exist within a Broad Portfolio as a quasi-independent entity. AMPs are established with clinical partners to address specific health needs of Veterans taking existing discoveries to implementation. They are narrower in scope and address critical problems to Veterans that can be translated from the lab to the clinic and/or inform healthcare decision-making. They foster multidisciplinary, team-based research that brings together experts and stakeholders from across the enterprise and can address urgent/immediate needs for Veterans and the public.

Dr. Bever displayed the organizational structure of ISRM, which consists of Broad Portfolios, AMPs, Operations, and Research Integration, all with the goal of replacing silos. There will be a Director of Research Integration to coordinate activities across and between the AMPs and Broad Portfolios. There is also an administrative support unit, or operations support unit, which will

provide administrative support functions for ISRM. Dr. Bever shared the ISRM timeline, which is currently in the middle of its length. Prototype portfolios have been stood up to test different approaches, and two tabletop modeling exercises to explore system and fiscal changes were conducted. The full transition from Services to Portfolios is targeted for completion in October 2024.

Dr. Bever provided an overview of the Military Exposures Research Program (MERP) and mentioned that Dr. Karen Block did the foundational work to stand this up. MERP seeks to advance military exposure assessments and understand the effects of miliary exposures on Veterans' health outcomes to inform care and policy. Military exposures refer to contact with toxic agents, singly or in combination, incurred through military service (Deployment, Occupation, or Garrison). Exposure assessment refers to identifying and quantifying toxic agent(s) to which a Veteran was exposed during military service. Dr. Bever introduced Rudolph (Rudy) C. Johnson, Ph.D. as the new MERP Director. Dr. Johnson brings 20 years of experience with the CDC to ORD.

Dr. Bever introduced Dr. Stuart Hoffman to discuss the Traumatic Brain Injury (TBI) AMP and its need for clinical collaboration. Governance for the AMP will consist of leaders on the clinical side, maintained through an executive structure that will provide information to the AMP and receive information back regarding clinical needs. Dr Hoffman described infrastructure and how ORD actualizes the Learning Healthcare System through the AMP structure. Infrastructure includes coordination centers, research coordinators, time support for clinicians, materials (i.e., imaging), and the pathways for communication of research across service lines. There are multiple sets of clinicians who need to integrate efforts to be successful. The structure of the AMP builds upon what has been established between ORD and the clinical side and utilizes communication to drive research and clinical care. Investing in the infrastructure is crucial for success.

Dr. Hoffman described the complex nature of TBIs as one that is especially difficult for Veterans to navigate. Over one third of individuals with a confirmed brain injury sustained their first TBI before the age of 18 and proceeded to receive additional exposures in training and combat. This leads to problems that affect both mental and physical health and well-being. TBI can stem from a Veteran's life-long history of injury or exposure and present itself in both moderate and severe forms. Long-term effects of TBI can manifest as neurodegeneration and chronic inflammation. TBI has many co-occurring conditions including sensory (peripheral or central), psychological, Post-Traumatic Stress Disorder (PTSD), depression, Substance Use Disorder (SUD), suicide, chronic pain, mobility, traumatic amputation, Spinal Cord Injury (SCI). Directly TBI also involves cognitive and executive dysfunction, effort control impairment, and endocrine dysfunction. The complexity of TBI was demonstrated in 2009 and mental health and physical medicine treatments remain today.

One of the major aspects of TBI is how it integrates with clinical care. According to Section 305 of the John Scott Hannon Act, the VA will fund an initiative to identify, validate, and integrate brain and mental health biomarkers among Veterans, launching the "Precision Medicine for Veterans Initiative". The studies will include brain structure and function measurements, such as functional magnetic resonance imaging (fMRI)and electroencephalogram. Ongoing clinical research efforts include the Long-term Impact of Military-relevant Brain Injury Consortium-Chronic Effects of Neurotrauma Consortium (LIMBIC-CENCE) and the Translational Research Center for TBI and Stress Disorders (TRACTS).

To meet the letter of legislation, four proof of concept proposals are being stood up. One has received funding already, and the others await approval. These four studies will be used to create predictive algorithms, diagnostic algorithms, and algorithms that will determine whether there is efficacy in the trials being done. Previously, TBI research in ORD was scattered across the four services. By standing up a TBI AMP, ORD can bring all studies under single oversight. This will help with strategic focus, increased collaboration, consistent purview guidance, and increased opportunity for translational impact on Veteran care.

The purpose of standing up the TBI AMP is to strategically identify and fund research that seeks to answer specific, real-world questions that are important to Veterans, providers, and/or the healthcare system that results in the improvement of health care, and well-being of Veterans with TBI and ensure that scientific research discoveries within the portfolio translate into clinical practice and inform healthcare decision making. The TBI AMP lead is Dr. Stuart Hoffman, who has 30 years of TBI and behavioral neuroscience research experience. There are three core Scientific Portfolio Managers (SPMs) with current TBI-focused portfolios, plus five consulting SPMs representing AMPs and existing portfolios of mental health, suicide prevention, pain/opioid use, and neurodegeneration/dementia that can include TBI projects. Dr. Hoffman displayed the different ways TBI research collaborates based on the complex nature of TBI. Collaborations include the Pain/Opioid use AMP, the Rehabilitation and Reintegration Broad Portfolio, and the Suicide Prevention AMP. He shared examples of how current AMP structure and continued investment can better support outcomes for Veterans with TBI.

Mr. Matthew Kuntz asked why Precision Oncology and Military Exposures were in separate entities. Dr. Bever explained that Precision Oncology and Military Exposures are separate because Military Exposures result in a variety of outcomes, including causing cancer, so ORD would need to consider all the outcomes of Military Exposures as well as many causes for cancer. Dr. Dubinett added that the LPOP is un-siloed, and in its initiation, there is a program that links clinical activities with research in a way that led to a transformation in screening. No other system in the country has been able to do this. They discovered a screening methodology that reduced lung cancer mortality by 20%.

Mr. Thomas Zampieri asked where diagnostic technology innovation research lives in the Enterprise Transformation. Dr. Bever responded that diagnostic technology innovation is

important in many of the portfolios and cross-cutting programs. Dr. Ramoni added that Dr. Bever has been working to create an ecosystem with more interaction among groups. ORD has benefited from communities that focus on disciplines, like Health Services Research or Rehabilitation Research. In this transformation, they are working to foster other discipline-based communities as well. Regarding diagnostic technology innovation within Precision Oncology, much of the work is done within the working groups, and more broadly diagnostic technology innovation would happen within more of the Broad Portfolios. Dr. Ramoni welcomed suggestions on how to foster the different communities.

Dr. Dubinett added that LPOP plans to run a diagnostic algorithm generated by collaborators at Massachusetts Institute of Technology (MIT) that predicts risk of lung cancer with a high-performance characteristic. They plan to run this in the background while checking blood and nasal epithelium for biological and molecular markers for risk. This is an important opportunity to determine risk, understand heterogeneity of risk and address lung cancer at the risk stage instead of the treatment stage.

Dr. Poropatich introduced Wendy Tenhula to present an overview of the process for NRAC to make recommendations to Secretary of the VA (SECVA). Dr. Tenhula explained that in general, Federal Advisory Committees (FACs) like the NRAC make recommendations to the SECVA. It is not a requirement but it's something that the NRAC has done in the past. The recommendations can result in significant improvements in service and provide important perspectives or viewpoints that affect VA operations. The supporting administration or program office is responsible for coordinating an official response after a formal recommendation is made and must respond within 120 days. They can concur in principle and meaning and in concept, but they are not able to implement; responses must go through a formal process for submission to the SECVA's Office and to Congress.

Dr. Poropatich emphasized the importance of the NRAC contributing to efforts in a meaningful way and agreed that generating formal recommendation could be a way to do this. He believes ORD is under-utilizing the expertise of the NRAC in many ways. He described the experts serving on the NRAC as including deans of major medical schools, clinical scientists, retired military leaders and Veterans who in aggregate possess a breadth of knowledge that can lead to change. He stressed the importance of acknowledging this point to the NRAC and invited thoughts on the topic from NRAC members. Mr. Kuntz responded that he believes the relationship between the NRAC and ORD at this time does not have the foundation to support the generation of recommendations.

Dr. Ramoni requested specifics on how to foster relationships between ORD and NRAC members. Dr. Poropatich recommended initiating with communication among parties. He suggested Dr. Williams pursue active outreach to solicit offline, individual feedback from NRAC members to assess whether they feel their time is valued. Other suggestions were to have the SECVA on a call to introduce members of the NRAC to him. The SECVA or one of his key

representatives could be invited to attend an in-person NRAC Meeting. Additionally, Dr. Poropatich suggested ORD pose questions to the NRAC about specific areas where help is needed. Options for distributing an agenda driven by the committee, sending presentations with annotations and questions for the committee prior to the NRAC Quarterly Meetings, and engaging in ongoings discussion about issues that are important to the committee were discussed.

Dr. Paula Schnurr asked if the committee needs to wait until March to hold an in-person meeting. Dr. Poropatich responded that due to logistics and travel time, March would be the earliest feasible date for all members to attend. Dr. Ramoni stated that she will create a one-page plan for NRAC to get back on track to share with the committee before the December meeting.

Next to present was Dr. Holly Krull, Interim Director, Biomedical Laboratory Research and Development. She discussed the VA Science and Health Initiative to Combat Infectious and Life-Threatening Diseases (SHIELD), the Air Force Health Study, and the Warren Collection. Dr. Krull clarified these are two sample collections of specimens and associated data that are looking for a new custodian and stewardship. VA SHIELD is a biorepository that has been stood up by ORD to facilitate research. They have been given the opportunity to take the specimens from these important collections into VA SHIELD. She informed the NRAC that one of her goals in presenting was to seek their advice and leadership on next steps.

The bottom-line up front is the question of whether ORD's biorepository system, VA SHIELD, is an appropriate location for preservation and research management of two legacy specimen collections currently held outside VA. Additional questions include the following. 1) Will NRAC design a steering and leadership committee (perhaps an NRAC subcommittee) to guide new use of these legacy specimen collections for research? 2) Are these specimens likely to be usable given storage conditions? 3) Is the Warren Collection of value for research? Dr. Krull requested guidance on how to stand up a governance structure to facilitate research.

Dr. Krull provided background information on VA SHIELD. VA SHIELD is a comprehensive, secure biorepository collecting specimens and associated data related to diseases of concern to Veterans. These specimens and data are available to VA investigators to advance the development of diagnostic, therapeutic and preventative strategies for use in clinical care. VA SHIELD was established in the fall of 2020 by the Veterans Health Administration (VHA) with a system wide comprehensive biorepository collecting specimens for research on COVID-19. It has grown to be:

- A model repository for other diseases and conditions affecting Veterans.
- A way to enhance collaboration with external partners focused on COVID-19 and other emerging infectious disease research.
- A mechanism to harmonize specimen and data collection procedures across multiple VA clinical sites.
- A way to launch flexible response to dynamic disease occurrences.

Dr. Krull shared a timeline of VA SHIELD Development, showcasing the methodical process of standing up the initiative. Developments began in August of 2020 with the most recent progress being the Umbrella Protocol approval, which allows for collection of consented specimens. VA SHIELD Governing Documents include the IRB-approved protocol, standard operating procedures, the Executive Steering Committee Charter, Programmatic and Scientific Review Board Charter, and the Federation Kit with set procedures for adding new sites to the VA SHIELD program.

Current objectives of VA SHIELD are to the use the infrastructure to collect high quality biospecimens from Veterans to enhance and accelerate research projects in high yield key research areas to provide VA investigators and collaborators with reliable, valid study materials. VA SHIELD also aims to develop a sustainable strategic research engine using bio samples collected under the Umbrella protocol, and to advance current capabilities by adding Legacy Collections. There is a set of facilities, collections sites, biobanks and coordinating centers across the country.

Dr Krull introduced the two legacy studies relevant to the discussion. The Air Force Health Study, ('Ranch Hand' Study) is a 20-year (1982-2002) study of airmen versus unexposed controls who participated in the Vietnam War's Operation Ranch Hand, spraying herbicides from fixed wing aircraft to fix foliage and destroy enemy crops for tactical miliary purposes. Assets include questionnaires, physical examination records, medical record data, 90 thousand specimens, medical images, and more. At the direction of Congress, assets were under Institute of Medicine (IOM) management from 2007-2015 to conduct additional research, preserve, and protect the assets. VA funded the IOM-managed research and paid for biospecimen support by the Air Force.

The Warren Collection is a late 1940s-early 1950s collection of serum (41,000 vials) and data from airmen with streptococcal infections who presented to clinics at Warren Air Force Base, Cheyenne, WY. Studies using the airmen's data defined the natural history and found effective treatment for streptococcal infections. Sera and data were used to identify long-term health consequences of hepatitis C infection.

Data from both studies are archived at National Academies of Sciences, Engineering, and Medicine (NASEM) and biospecimens are managed in negative seventy-degree freezers at Wright-Patterson Air Force Base. Both NASEM and the Air Force are looking to find new custodians and stewards for these assets. The Vietnam Veterans of America are championing to preserve the specimens and associated research. In the past, VA has made efforts to find new custodians and stewardships for these specimens. The new Stakeholder Group's recommendation is to move these assets to VA SHIELD and make them available for research.

The NRAC originally considered the research value of the AFHS in 2016. At that time the NRAC formed a subcommittee and made recommendations associated with it. The overall recommendation was that "A research program based on the AFHS biospecimens, and data can

be continued, and that research proposals (for either pilot or full studies) using the AFHS biospecimens and data can be accepted and funded after satisfactory scientific peer review". The subcommittee conclusions were as follows:

- It is possible to manage the AFHS assets and perform high-quality scientific research with them.
- Sustaining access to the AFHS biospecimens and data repository benefits the Veteran community and the public at large, who gain from the information derived from studies of the assets.
- The AFHS assets have been underutilized, and the custodian should continue to seek ways to improve management approaches to maximize the use of this resource in research.
- It is feasible and advisable to maintain the AFHS data and biospecimens and make them available for continued use in research.

In 2021 a large and diverse Stakeholder Group was brought together to preserve biospecimens, ensuring they are usable for research, and then creating a collaborative environment to have this research move forward. The Stakeholder Group embodied a thoughtful process, bringing together a group of diverse, invested individuals who broke into various subgroups to look at research, biospecimen management, data, and advocacy and education. Stakeholders suggested that subject matter experts (SMEs) share their experiences with the various subgroups. A recommendations' report was created and delivered to the CRADO and to the Assistant Undersecretary of Health-Discovery, Education and Affiliate Networks (AUSH-DEAN). The Stakeholders recommended that VA SHIELD be the custodian, or steward, of these assets. AUSH DEAN and CRADO's response to the recommendation was to create reliable and high-quality long-term stewardship of the Air Force Health Study samples as part of an active research program, make curated data available to qualified researchers inside and outside of VA, and catalyze high-quality research on the Air Force Study assets.

However, prior to taking on this opportunity, Dr. Krull feels it is necessary to be cognizant of how to move forward and the implications of taking on these biospecimens. She has come to the NRAC for review of VA SHIELD as a suitable biorepository, looking at a governance structure to make sure they utilize specimens properly and respectfully. She is seeking guidance on the usability and quality of the biospecimen as well as the value of the Warren Collection for research. They were also tasked with developing a budget and a timeline to move forward with this work, and whether funding qualifies under the toxic exposure funding mechanisms and lastly looking at prework before specimens were transferred.

Dr. Krull concluded her presentation by reiterating the charge to the NRAC and provided a tentative timeline for a potential subcommittee. By January of 2024, an NRAC subcommittee would be formed, and include stakeholders from the Vietnam Veterans of America (VVA), NASEM, Air Force, academia, and independent subject matter experts on biorepositories. The

NRAC subcommittee would complete the evaluation of VA SHIELD as a biorepository system capable of storing and managing the Air Force Health Study and Warren Collection for research. By March 2024, the NRAC would advise on the current state of the biospecimens and the research value of the Warren Collection and schedule the first leadership and guidance meeting for the VA's new research stewardship of the AFHS/WC.

Dr. Poropatich thanked Dr. Krull for her presentation and opened the floor to questions. He noted there are already biorepositories for specimens in the Department of Defense (DOD) at the Joint Trauma Registry. He asked Dr. Krull if she had investigated how those entities work with current biorepositories. Additionally, he questioned if there was set aside, committed funding from VA to do research with the data, and if research themes were identified. For the value of the research, it may be hard to see how viable the specimens are at their current stage. He asked what role governance leads played in already answering some of the same questions Dr. Krull is asking the NRAC.

Mr. James Poel, a retired Air Force Public Health Officer, spoke in response to some of the questions. He worked to relocate the specimens previously and at that time contacted all government and non-government laboratories that NASEM recommended in their final report as well as every DoD repository available. Each lab – government, academic and DoD – required a significant amount of funding to update their infrastructure or rearrange the process by which they currently process specimens they already have to accommodate these new specimens. They spoke with leadership at DoD repositories Dr. Poropatich referenced. They all said the specimens were valuable for medical research, but they either needed money the Air Force did not have, or that DoD had not budgeted for. University of Texas at San Antonio has some of the researchers who worked on the initial Air Force Study, and they budgeted about $12 million to rearrange the infrastructure to accommodate the specimens.

Dr. Poropatich said that it is unclear what types of specimens are in the biorepository. Mr. Poel confirmed there is adipose tissue and semen. These samples were taken over the course of five to six in person exams of about 2,500 Vietnam Veterans. Dr. Robert Bonomo added that Case Western Reserve University has members in the Department of Neurology performing cancer research who are very interested in these samples. Dr. Krull added that the Stakeholder Group found it important that the research plan was developed, and she recommended facilitating a state-of-the-art symposium bringing together interested investigators from across the country to look at developing a series of research themes and projects to move the research forward.

Dr. Poropatich concurred the value of the specimens is significant, but funding would be the largest barrier with determining who will manage the research as an additional barrier. Organizing the meeting and academic interest while reaching out to the legislature cannot be a VA-led effort. There is an opportunity here for VA Office of Academic Affiliations. The VA NAAC (National Academic Affiliations Council) could bring in government affairs personnel to develop a white paper to Congress. There is concern that NRAC's focus on this would be a

heavy lift and pulling together a team, especially with four members stepping down in March, may be a challenge.

Dr. Kuntz echoed Dr. Poropatich' s thoughts and asked if NRAC members should vote on this matter. This may not be an effective biologic specimen analysis group, as this committee was not designed to do this type of work. Dr. Schnurr agreed this would be a heavy lift, in a short amount of time. Dr. Bever confirmed these are valuable specimens and ORD could fund projects that would shed light on the effects of the exposures. He said that VA, or ORD specifically, accepting the infrastructure and research costs would be challenging. However, the NRAC is able to make a recommendation to the SECVA about cost sharing. An agreement could be made with DoD and the Air Force so VA wouldn't have to bear the entire burden of cost.

Dr. Ramoni said the initial thought would be for the NRAC to form a subcommittee to offer an external perspective and make recommendations. However, she does agree that this is a heavy lift. Dr. Poropatich suggested to Dr. Williams that the NRAC could develop a one-to-two-page white paper through Dr. Krull summarizing the presentation and send the paper with the slide set to the NRAC members in an email. Members can then decide as a group who the interested individuals are who could lead a subcommittee.

Public Comment Period:

Dr. Rashi Romanov, CEO of the National Association of Veterans' Research and Educational Foundations (NAVREF) said having a window to hear the advocacy perspectives and what issues are rising to the top as priorities in VA/ORD is beneficial. Dr. Poropatich commented that NAVREF could be an important partner to collaborate with regarding VA SHIELD.

Next Meeting:

The next meeting of the NRAC will be held on December 6, 2023, from 11am to 2pm EST.

Action Items:

- Dr. Williams will solicit offline, individual feedback from NRAC members to assess whether they feel their time is valued.
- Consider agenda for future meetings be driven by the committee members.
- Consider sending presentations with annotations and questions for the committee prior to the NRAC Quarterly Meetings.
- Ongoing discussion between the NRAC and ORD be initiated about issues important to the committee.
- Dr. Ramoni will develop a one-page plan for the NRAC to get back on track with tasks before the December meeting.
- Dr. Williams will facilitate the development of a 1–2-page white paper through Dr. Krull summarizing the VA SHIELD presentation.

- The paper and presentation slides will be distributed to the NRAC members in an email. Members will decide as a group who the interested individuals are who could lead a subcommittee.

Adjournment:

The meeting was adjourned at 2:05pm ET.

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Ronald Poropatich
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10-30-2023 | 9:58 PM EDT

Ronald Poropatich, MD, MS
Chair, NRAC