

U.S. Department of Veterans Affairs

Office of Research and Development (ORD)

Quarterly Meeting of the National Research Advisory Council (NRAC)

March 6, 2024

Minutes

Committee Members Present

Dr. Ronald Poropatich, Chairman
Dr. Steven Dubinett
Matthew Kuntz, JD
Dr. Cato Laurencin
Dr. Rajeev
Ramchand Dr. Paula
Schnurr
Dr. Thomas Zampieri, PA
Dr. Sanjay Doddamani
Dr. Kent Kester
Dr. Dallas Hack
Dr. Steven Dubinett

Committee Members Excused

Dr. Melinda Kibbe
Dr. Julie Tomaska

Speakers/Presenters

Dr. Ronald Poropatich, Chairman
Dr. Rachel Ramoni
Dr. Allison Williams, Designated Federal Officer (DFO)
Dr. Carolyn Clancy
Dr. George Lathrop
Dr. Wendy Tenhula
Mr. Marc Wynne
Dr. Victoria Davey
Ms. Rashi Venkataraman Romanoff
Mr. Christopher A. Britt
Dr. Miriam Smyth
Mr. Jester Jersey
Dr. Susan Sisley
Mr. Todd Scattini
Mr. Ray Brooks
Ms. Emily Blair

Attendees

Dr. Allison Williams, DFO

Rashelle Robinson, Alternate DFO
Kristan Buotte, Contractor/Note-Taker

The virtual meeting of VA's National Research Advisory Council (NRAC) took place on March 6, 2024. Dr. Allison Williams DFO, called the meeting to order at 9:00 AM EST and introduced the Chair, Dr Ronald Poropatich. Dr. Poropatich took a moment to express his gratitude towards Dr. Allison Williams, DFO, and Rashelle Robinson, Alternate DFO, for their hard work in organizing the NRAC meetings. Dr. Poropatich then introduced Dr. Carolyn Clancy, Assistant Under Secretary of Health, Discovery Education and Affiliate Networks. Dr. Poropatich emphasized the importance of Dr. Clancy's perspectives and invited her to provide opening comments.

Dr. Clancy began by expressing her profound appreciation for the work that the NRAC is a part of. She stressed the importance of an advisory council to support a strong research program and recognized the significant commitment of time and effort made by individuals in helping address complex and sometimes challenging issues, which ultimately benefit the Veterans being served. She noted that the upcoming discussions were to include updates on the information regarding VA Science and Health Initiative to Combat Infectious and Life-Threatening Diseases (VA SHIELD) and the Air Force Health Study (AFHS), which have both been previously discussed in prior meetings. The AFHS is at a pivotal moment, particularly with the involvement of the Vietnam Veterans of America, who are deeply invested in their legacy and support for fellow Veterans. Dr. Clancy initiated the proposal to establish an advisory group linked to the overarching advisory group, preferably as a subcommittee, to ensure a cohesive approach. Dr. Clancy reiterated her support for this approach and encouraged full consideration from the participants. Dr. Clancy concluded her introduction by expressing gratitude once again for everyone's involvement and contributions.

Dr. Poropatich shifted to discussing the NRAC members who will be departing the committee. These members have contributed to the NRAC for many years and have made significant contributions to the care of Veterans. Included in this group of departing members is Dr. Sanjay Doddamani, Dr. Steven Dubinett, Matthew Kuntz, JD, Dr. Paula Schnurr, and Dr. Poropatich, himself. Dr. Poropatich thanked these departing members for the time and effort they have dedicated to the NRAC. Dr Kent Kester had also joined the committee and was present during the call. New members will be added to the committee. Their nominations are currently undergoing review.

Dr. Sanjay Doddamani expressed his gratitude for the opportunity to engage with the active research and budgeting considerations discussed by the committee over the past several years. He acknowledged the challenges posed by the COVID-19 pandemic in maintaining momentum and connection to the agenda, particularly with the inability to meet in person.

Dr. Allison Williams shared a video that included remarks from Mr. Denis McDonough, Secretary of VA. This message was a public service announcement to all committees. Secretary McDonough expressed gratitude for the hard work of the federal advisory committees and underlined the crucial role of committee members in providing advice

and recommendations to ensure the delivery of effective support for Veterans. This task, he noted, should be approached with passion and professionalism to aid Veterans when they are most in need. He called for focused commitment and actionable ideas from committee members to enhance VA benefits and services, ultimately aiming for a stronger, more effective VA. He emphasized the importance of specific critiques and advice to drive improvement, as well as the responsibility to recommend qualified and diverse individuals to continue the work. The values of integrity, commitment, advocacy, respect, and excellence were highlighted as guiding principles for all decisions and recommendations. VA will always deal with Veterans, Veteran advocates, and all Veteran organizations with integrity and VA must commit to ensuring everything they do best serves Veterans and their access to resources. VA will be the leading advocate for Veterans, their families, caregivers, and survivors in everything it does, and VA will always provide all Veterans with the respect and professionalism that they deserve. He continued by highlighting that Veterans must feel safe and welcome at every VA facility and VA will welcome every Veteran, including women, Veterans of color, LGBTQ+ Veterans, and make sure every person entering a VA facility feels safe, free of harassment, free of discrimination. Secretary McDonough concluded by highlighting the lifesaving work that VA's committees have done, emphasizing the single result that matters most is the Veterans' lives saved and the Veterans' lives improved. Dr. Poropatich acknowledged the inspiring words from Secretary McDonough and welcomed Dr. Rachel Ramoni, Chief Research and Development Officer (CRADO), to provide updates on VA research.

Dr. Ramoni echoed Secretary McDonough's sentiments in thanking the committee for their service to Veterans and Veteran health care. She expressed the significance of face-to-face meetings, while remarking on the inability of the current iteration of the committee to meet in person due to the pandemic and subsequent budgetary constraints. However, she conveyed determination to strive for an in-person meeting later in the year. As the current committee term comes to a close, Dr. Ramoni acknowledged and thanked the members for their service, particularly recognizing Dr. Poropatich for his leadership during tumultuous times. Dr. Poropatich's contributions were highlighted, including support for various subcommittees, and providing valuable insights to improve committee proceedings. She also appreciated the ongoing commitment of members, and anticipates the addition of new members and a new Chair in the coming weeks. She emphasized the profound contributions made by both current and future members to serve Veterans effectively within and outside the committee.

Dr. Ramoni highlighted the advocacy and recommendations regarding the conflict-of-interest rules that were addressed in the Cleland Dole Act a year prior. This law resolved a conflict of interest for VA researchers related to compensation from non-VA sources and addressed many other longstanding challenges facing VA research. The committee's support was vital to addressing these issues and it will be critical again on a new conflict of interest issue raised by the Office of General Counsel Ethics Specialty Team. Dr. Ramoni noted that Dr. George Lathrop would present an update on the work of the Sensitive Species Subcommittee, with recommendations for the committee's consideration. She highlighted the ongoing importance of the committee's advocacy in accelerating the translation of research into clinical practice. Dr.

Ramoni reiterated that the goal is the well-being of Veterans and their loved ones, highlighting strides made in various areas as shown in the FY23 Office of Research and Development (ORD) Annual Report. She mentioned the growing interest in the use of psychedelic-assisted therapy for mental health conditions, and highlighted evidence of effectiveness and the potential for Food and Drug Administration (FDA) approval, noting that Dr. Miriam Smyth would provide an update on this work during the meeting. Dr. Ramoni acknowledged the privilege of having individuals planning to address the committee about these treatments during the public comment period. She underlined the importance of VA research in the nation's biomedical ecosystem, mentioning recent contributions to initiatives such as Cancer Moonshot, monkeypox, and COVID-19. Collaboration with academia, industry, and other external partners was emphasized, with a note on VA nonprofit corporations as vital partners. Ms. Romanoff, the Chief Executive Officer (CEO) of the National VA Research and Education Foundation, also known as NAVREF, would provide insights into the role of VA nonprofit corporations. Looking ahead to 2024, Dr. Ramoni expressed excitement for the continued work with the NRAC, who will make substantial contributions toward improving the well-being of Veterans and their loved ones. Dr. Ramoni thanked the members for their service and extended a warm welcome to members of the public who joined the meeting.

Dr. Poropatich thanked Dr. Ramoni and turned the meeting back over to Dr. Williams to share how the agenda for this meeting was assembled. Dr. Williams discussed feedback from the October and December meetings, noting a strong interest in increased NRAC member engagement in shaping the agenda and topics relevant to NRAC and ORD. To address this, themes from the December meeting were summarized, and a survey was developed and sent to all NRAC members. The survey allowed members to participate in selecting agenda items and setting forth the agenda for the year. Dr. Williams presented the themes and topics evaluated in the survey and shared the survey results, expressing gratitude to all members for their participation. While the agenda was not perfectly aligned with the survey results, the majority of selected topics were heavily favored. Dr. Williams highlighted comments from members, including the importance of explaining the role of parent and subcommittees, and identifying priority topics such as: issues facing Black and Latino Veterans, mental health, homelessness among Veterans, and increasing national awareness of VA research efforts. She emphasized the importance of public awareness and collaboration in achieving the ORD mission, particularly considering ORD transformations. Dr. Williams concluded by thanking individuals involved in the agenda-building process and outlined plans to continue incorporating feedback to ensure alignment with ORD and NRAC interests.

Dr. Poropatich followed up on Dr. William's discussion by adding the importance of the NRAC to identify the onboarding process for new members to ensure their understanding of their role, their relationship to ORD, the Academic Advisory Council, the subcommittees, and the responsibility of the NRAC along with its expectations. He recommended onboarding new members offline, so they have adequate preparation prior to the next meeting. With no comments or issues presented from the members, Dr. Poropatich turned the discussion over to Dr. Wendy Tenhula, Deputy CRADO for Operations and Workplace Culture and Mr. Marc Wynne, Deputy CRADO for Strategy, Partnership, Outreach and Communications.

Mr. Wynne shared a summary of the 2023 NRAC Annual Report. The purpose of this report is to aid the NRAC in their evaluation of the scope and focus of the VA research portfolio. The VA research program should be evaluated by the NRAC for appropriate portfolio balance and program management. Success of the VA research program should encompass three goals:

1. The program should push the science in areas of Veteran-specific needs such as Traumatic Brain Injury (TBI), Post Traumatic Stress Disorder (PTSD), military exposures, and suicide prevention to unlock new treatments and bring about advances in care.
2. The program's success should be demonstrated through improvements to how care is organized and delivered in VA.
3. The program should recruit, train, and retain the best researchers, especially those from different backgrounds that represent the Veterans served, with skills in cutting-edge areas.

Mr. Wynne transitioned to an overview of performance in fiscal year 2023. There were 105 active research sites and nearly 7,500 actively funded research projects. The total congressional appropriation for medical and prosthetic research stood at \$916 million, contributing to a total research budget of \$2.3 billion. Additionally, over 11,000 research articles were published during this period. Regarding communication, web statistics indicate improvements in recent years and reflect increased engagement. Outreach to both internal and external stakeholders increased significantly in 2023. Specifically, the number of overall unique users to the website and the research pages increased, as did the number of sessions or encounters. Total page views for research news indicate that more people visited and engaged with the research. Mr. Wynne noted that the report contains summaries of 18 ORD initiatives. However, the focus was on highlighting key aspects of half of them, including six cross-cutting clinical priorities and three high-priority special emphasis initiatives. Due to time constraints, each topic was addressed briefly, and attendees were encouraged to refer to the slide deck or the annual report for a more comprehensive overview. Questions regarding the report or presentation content can be submitted for clarification by the relevant subject matter expert.

Mr. Wynne began with military exposure environmental exposures, highlighting the objectives of the Military Exposures Research Program (MERP) to improve individual exposure assessments for informing care, policy, and ongoing research. In 2023, accomplishments included demonstrating differences in exposures based on service settings through a scientific survey, as well as developing a research database of individuals who served in the Vietnam era. Important research findings from MERP in 2023 indicated that the PACT Act improved care for Veterans with environmental exposures and mitigated feelings of institutional betrayal. Additionally, exposure to burn pit or military inhalants was linked to increased risk of breathing issues and chronic bronchitis.

Traumatic Brain Injury (TBI) was emphasized as a signature injury of the Iraq and Afghanistan wars, with potential lifelong disabilities varying by severity. Accomplishments in 2023 included initiating a collaborative network to integrate biomarkers, imaging, and

physiological measures for diagnosis and monitoring of complex TBI-related brain and mental health conditions. Notably, TBI was associated with increased suicide risk, mental health conditions, and impaired work functions, with implications for the substantial number of Veterans receiving compensation for TBI and tinnitus.

Regarding VA Cancer Research, Precision Oncology was highlighted as a key emphasis program, aligning with the President's Cancer Moonshot initiative. Accomplishments in 2023 included initiating new bladder cancer clinical trials, expanding lung cancer screening sites, and developing novel therapeutic trials for advanced non-small cell lung cancer. Research findings revealed disparities in late-stage pancreatic cancer diagnosis and treatment between Black and White Veterans, as well as a potential link between genetic predisposition for cannabis use disorder and lung cancer.

Preventing suicide is a national public health priority, and is critical to the health and well-being of Veterans. Accomplishments related to suicide prevention in 2023 include contributing to the Suicide Prevention Trials Database, expanding the Suicide Prevention Research Impact Network (SPRINT), and funding research to better understand suicide risk associated with opioid discontinuation. Research findings revealed that rates of suicidal thoughts among Veterans decreased after the onset of the COVID-19 pandemic, and Veterans with food insecurity had significantly higher rates of suicidal ideation, particularly when coupled with a mental health disorder.

Chronic pain, which is more prevalent and of greater intensity in the Veteran population, was addressed with various initiatives in 2023, such as the Cartilage Repair Strategies Symposium and a funded Veterans Integrated Services Network (VISN) Partnership initiative. Research findings highlighted that homeless Veterans were more likely to possess dangerous combinations of benzodiazepine and opioid prescriptions.

In the realm of PTSD research, accomplishments included the launch of a telehealth program for rural veterans with PTSD and the identification of novel genetic variants associated with re-experiencing symptoms. Notably, research findings indicated low rates of Veterans initiating PTSD treatment within the first year of diagnosis and a significant proportion of Veterans experiencing PTSD-related stress at the end of their lives.

Mental health research, supported by enhancements in programs included in the Commander John Scott Hannon Mental Health Care Improvement Act, focused on diverse areas such as opioid and benzodiazepine-related mortality, the association of altitude with suicide, and the discontinuation of antidepressants during pregnancy among Veterans.

The Million Veteran Program (MVP) reached a milestone of one million Veterans enrolled and made data accessible to VA researchers. Noteworthy research findings from MVP in 2023 include the identification of gene variants associated with suicide attempts and a gene mutation linked to lower risk of chronic kidney disease in Black patients.

Finally, accomplishments related to tinnitus and hearing loss included the development of a tinnitus clinical decision guide and the initiation of a longitudinal study to evaluate

auditory functioning in post-9/11 Veterans. Research findings highlighted the significant impact of tinnitus on ear synapse loss and the potential efficacy of minimal residual inhibition therapy in reducing Veterans' reactions to tinnitus.

Mr. Wynne concluded by stating that the VA Research Program's performance in terms of portfolio balance and program management is believed to have adequately satisfied evaluation criteria. The NRAC is now required to grade the program's performance based on the criteria for a portfolio balance. Dr. Poropatich suggested distilling down the 18 topic areas into the top 3-5 accomplishments that have the greatest impact on Veteran health. He reminded NRAC members to take note of any important topics discussed during the meeting that they wish to explore further at the next meeting. They are encouraged to communicate these topics to Dr. Williams to ensure they are included in the agenda for the upcoming meetings. This proactive approach will help in prioritizing and addressing key issues effectively in future meetings. Dr. Williams communicated that a survey will be distributed via electronic mail to members after the meeting so they may provide their ratings.

Dr. Poropatich introduced Dr. Victoria Davey, Associate CRADO, Epidemiology and Public Health, to discuss the VA SHIELD and Air Force Health Study Assets. Dr. Davey reiterated that they are seeking assistance in making decisions concerning the two significant legacy collections. They propose the creation of a subcommittee composed of NRAC members along with external individuals possessing relevant expertise to evaluate whether VA SHIELD, the national biorepository system, is prepared to handle the data and biospecimens from these collections. Specifically, they need to determine if VA should accept custody of the Air Force Health Study and Warren Collection and what testing, if any, should be conducted on the samples before acceptance. Additionally, they seek guidance from NRAC on the maintenance and utilization of these legacy collections for future research endeavors. The Air Force Health Study spans several years and includes extensive military, clinical, and biospecimen data from Vietnam Veteran Air Force crew members involved in herbicide missions during the Vietnam War. The Warren Collection consists of biospecimens from 9,000 recruits who had Group A streptococcus infections between 1947 and 1952. Both collections hold significant research value and are at risk of loss if not properly preserved and managed.

An NRAC review offers several advantages, including the inclusion of non-members with specific expertise to provide independent advice. This approach ensures a measured and informed decision-making process that respects the interests of researchers and Veterans alike. The NRAC subcommittee would review existing recommendations, request additional information as needed, and develop a timeline for decision-making. The subcommittee would then report its findings to NRAC for further action. In summary, they turn to NRAC for evaluation and guidance on the readiness of VA SHIELD to handle these collections, the acceptance of the Warren Collection, testing requirements for samples, and guidance for maintenance and use of the collections for research. The proposed subcommittee will consist of NRAC members and external experts, with reporting to NRAC at least annually. Dr. Davey extended appreciation for attention and welcomed any questions or feedback.

Dr. Poropatich recognized the importance of the issue at hand for VA and assured that the NRAC is committed to providing thorough analysis and thoughtful contributions to the subcommittee. However, he shared his uncertainty regarding the structure of the subcommittee and the role of NRAC members within it. Specifically, it was unclear to Dr. Poropatich if the subcommittee should be led solely by NRAC members or if it should include preexisting individuals who have been working on the issue. He requested clarification on how the subcommittee will be structured and how NRAC members will be integrated into the process. Given the complexity of the issue and the extensive prior work done on it, he expressed concern about the expectations for new NRAC members who may not have the same level of understanding as those who have been involved for years.

Dr. Davey clarified that she envisions an NRAC member to lead the subcommittee, that will be staffed by available experts who have familiarity with the work. The NRAC members would complement a preexisting group of VA scientists and clinicians, forming a subcommittee officially. This subcommittee, like others discussed during the meeting, would be composed of a preexisting group already actively involved in addressing the issue. She added that it is important to note that while the focus would be primarily on scientific expertise, the group would also include stakeholder input. Dr. Poropatich recommended offering an informal NRAC meeting to discuss the VA SHIELD biorepository effort with the new members and consider their interests in forming a subcommittee. Dr. Williams stated that substantive discussions and actions may occur only at a convened meeting. She indicated that the motion at hand was to vote on the authorization of a subcommittee and following that, they will determine what NRAC members, if any, would be part of it. Dr. Williams clarified that there is no requirement for any NRAC members to serve on the subcommittee, though they may do so. Dr. Poropatich motioned to form a subcommittee for the Air Force Health Study/Warren Collection. The motion was approved unanimously with no abstentions.

Dr. Poropatich then introduced the next speaker, Ms. Rashi Venkataraman Romanoff, CEO, National VA Research and Education Foundation (NAVREF). Ms. Romanoff began by explaining that thirty years ago, Congress collaborated with VA to establish a flexible funding mechanism aimed at ensuring access to promising phase two and phase three cancer care drugs for Veterans. This initiative gave rise to VA-affiliated nonprofits across the country. Today, there are over 75 such nonprofits, collectively facilitating over \$310 million in external investments into clinical research and education in FY22 alone. NAVREF, as a membership association representing these nonprofits, provides leadership training, core services, and education to support their efforts.

Despite VA's high value proposition of research, challenges persist. Less than 5% of clinical trials are offered at VA, highlighting the need to streamline processes and increase efficiency. While VA has made strides in this regard, challenges such as navigating complex regulatory frameworks and limited data availability remain. Nonprofits find themselves caught between various stakeholders, including the federal government, academic affiliates, and external sponsors. Addressing these challenges requires proactive measures. Enhancing VA's clinical data-sharing capabilities could make VA more attractive to external partners seeking to support Veterans. Proactively reaching out

to organizations working on research areas relevant to Veterans' needs could foster collaboration and expand clinical research opportunities at VA.

Additionally, addressing issues such as VA Interagency Personnel Act (IPA) agreements and concerns regarding Section 208 conflict-of-interest disclosures can ensure the financial stability and operational efficiency of VA-affiliated nonprofits. Expanding the capacity of VA's research opportunities and advocating for policies that support the VA research ecosystem are essential steps toward realizing these goals. By leveraging its strengths and addressing existing challenges, VA can further enhance its research capabilities and better serve the health care needs of Veterans.

Dr. Poropatich thanked Ms. Romanoff for highlighting the importance of the topics discussed. He concurred that issues such as VA IPAs and digital imaging and data sharing should be reviewed by the NRAC. He suggested Ms. Romanoff return to a future NRAC meeting to discuss more about these topics as VA begins to develop a digital imaging repository for radiology. Dr. Poropatich motioned to invite Ms. Romanoff back to expand upon some of the challenges raised in her presentation. The motion was approved unanimously without abstentions.

Dr. George Lathrop, Chief Veterinary Officer, presented next and provided an update on sensitive species research. He acknowledged the effectiveness of the enhanced review processes in managing research protocols, and elaborated on the current status of protocols in the system, noting that there is only one protocol involving client-owned animals in collaboration with the University of Pennsylvania. This protocol is undergoing thorough review and evaluation.

Moving on to appropriation bill issues, Dr. Lathrop raised concerns about a provision that will require VA to completely eliminate the use of sensitive species in VA research by March 2026. He emphasized the potential adverse effects of such a provision on critical research areas, particularly in regenerative spinal research and the treatment of paralyzed Veterans. Plans were outlined to address this issue through the creation of a comprehensive position paper and engagement with congressional stakeholders to advocate for the preservation of essential research avenues.

Dr. Lathrop delved into the interpretation of combat-related injuries and the pertinent legal framework, citing the relevant sections of 26 USC § 104(b)(3). He provided clarity on what constitutes combat-related injuries, emphasizing the broad scope of the definition encompassing injuries incurred during armed conflict or training exercises simulating war conditions. This interpretation suggested that many research initiatives impacting Veterans could be considered combat-related, offering insights into potential justifications for research endeavors. He underscored the importance of maintaining ethical standards in animal clinical trials, particularly those involving client-owned animals. He recommended continuing the established review process without abbreviations to ensure rigorous adherence to ethical guidelines and legal requirements.

Dr. Ramoni highlighted that the removal of VA's ability to conduct canine, feline, and nonhuman primates research opposes the direction that they have given before by

Congress. Dr. Ramoni's proposed next steps to NRAC regarding sensitive species were as follows:

1. ORD to distribute position paper to NRAC membership with regard to appropriations language that would eliminate VA's ability to conduct any research in sensitive species beyond spring of 2026.
2. Depending on what happens with the appropriations language, NRAC would have the opportunity to make its recommendations to the Secretary in the normal cycle.

Dr. Poropatich introduced the next speaker, Mr. Christopher Britt, Program Director, Research Integration and Training, Ethics Specialty Team, Office of General Counsel. Mr. Britt provided updated 18 U.S.C. § 208 Guidance for Researchers. He discussed the implications of 208, which is the primary conflict of interest statute governing federal employees, including those working within the VA Research Program. Historically, the interpretation and application of this statute by the Office of General Counsel (OGC) have been insufficient, leading to the need for a change in approach. The current practice has resulted in inadvertent conflicts of interest violations among VA researchers. The short-term solution has been the issuance of section 208 waivers, allowing employees to work on studies despite conflicts of interest.

The root cause of these violations lies in the statutory framework established by Congress, which mandates VA collaboration with affiliates and NPCs for clinical care, research, and education. This framework inevitably leads to conflicts of interest for VA researchers who also work at affiliate institutions or NPCs. Thus, a legislative fix is necessary to address this systemic issue. The presentation outlined the key points of section 208, emphasizing that federal employees cannot participate in a particular matter that affects certain financial interests, including those of their outside employers. The challenge lies in applying this statute to research, where the science, funding, and research agreements are intertwined. The traditional approach of separating the scientific aspect from other elements of research is no longer viable, requiring a new analytical framework.

Moving forward, VA intends to implement a new approach to address conflicts of interest in research, with a target date of the end of the current fiscal year. This will involve a collaborative effort between OGC, ORD, and other stakeholders to develop processes, guidance, and educational materials. Additionally, efforts will be made to advocate for a legislative fix to amend the statutory framework, allowing for greater collaboration without risking ethics violations. Mr. Britt concluded by highlighting the need for congressional support for a legislative fix, and the ongoing efforts to brief the HVAC and pursue a solution to the underlying issues with section 208.

Dr. Poropatich requested clarification on whether conflicts of interest arise when VA employee investigators conduct research at academic affiliates or when external researchers collaborate with VA and receive payment for their work. Dr Britt assured that if the individual is being asked to do work at the affiliate in their affiliate capacity, then section 208 does not come into play because it does not qualify as VA work. Dr Kester then asked about the potential conflicts of interest that may arise when a VA researcher

collaborates with an academic affiliate. Specifically, the inquiry focuses on situations where both the VA researcher and the academic affiliate researcher are funded by their respective institutions and collaborate on a project, such as an NIH or Department of Defense (DoD)-funded program. The question aims to understand how conflicts of interest are adjudicated in such scenarios and how the potential benefits to the affiliate's employer are evaluated. Dr. Britt responded that the primary example provided is when an NIH grant is administered by an academic affiliate, resulting in the affiliate earning revenue through indirect costs. In such cases, the study affects the affiliate's financial interests. If a VA employee participates in the study while also being employed by the affiliate, their involvement impacts their affiliate employer's financial interests, constituting a violation of section 208. The work group aims to identify other scenarios where research may affect affiliate financial interests and address them accordingly.

Dr. Poropatich asked Dr. Britt if there were any actions NRAC could take up until and during the next NRAC meeting to offer support. Dr. Poropatich suggested drafting a letter, with input from Dr. Chris Bever and Dr. Ramoni, expressing the concern about conflict-of-interest issues discussed. This letter would be sent through VA leadership channels to reach the Secretary of VA. The timing of sending the letter would depend on guidance from the two leaders. Dr. Ramoni added that there are two potential routes for addressing these concerns: through VA's own legislative proposals, which will be prioritized by the end of March with Secretary awareness being crucial, or through independent congressional action. It's important for Congress to understand the specific legislative language needed to address these challenges effectively. Dr. Poropatich motioned to have NRAC draft a letter with appropriate input from both internal and external sources to the Secretary of VA outlining a discussion on section 208 and its impact on conducting VA research. The motion was approved unanimously with one abstention.

Dr. Poropatich shifted to invite Dr. Miriam Smith, Director (Acting), Clinical Science Research and Development, to speak about the status of the research efforts in psychedelic assisted treatment. She began by sharing that a Food and Drug Administration (FDA) decision is expected on August 11, 2024 regarding MDMA's new drug application (NDA) for treating PTSD in conjunction with psychotherapy. This could potentially usher in a paradigm shift in mental health treatment. ORD has been diligently preparing for this potential new era in mental health care for Veterans. In recent years, there has been growing scientific evidence supporting the effectiveness of psychedelic assisted treatments. ORD has been collaborating with the Office of Mental Health and Suicide Prevention (OMHSP) to position VA for future psychedelic research and potential clinical implementation, especially for Veterans struggling with PTSD, depression, and substance abuse.

Psychedelics are a class of substances that alter consciousness or awareness, and they can be naturally occurring or synthetically produced. They focus primarily on two categories: classical psychedelics like psilocybin, LSD, and ayahuasca, which are serotonin 2A agonists, and empathogens or entactogens like MDMA. MDMA is particularly noteworthy due to the upcoming FDA decision. It's important to note that psychedelics are currently classified as Schedule I controlled substances by the Drug Enforcement Administration (DEA), meaning they have no accepted medical use and a high potential

for abuse. However, this classification may change pending the FDA decision. Despite this regulatory status, VA remains committed to exploring safe avenues for promoting Veterans' health, including psychedelic research. To summarize the FDA's actions regarding psychedelics, there has been significant activity in recent years, particularly with MDMA and psilocybin. The FDA granted breakthrough therapy status to MDMA in 2017, allowing for intensive guidance on clinical trials. Similar status was granted to psilocybin in 2018. Last month, the FDA accepted the NDA for MDMA from Lykos Therapeutics (formerly MAPS), which is scheduled for decision on August 11, 2024. If approved, this would mark a paradigm shift as the first MDMA-assisted therapy for PTSD in over two decades.

Currently, there are several active and completed studies on psychedelics involving Veteran participants at VA medical centers. Studies involving Schedule I substances require appropriate regulatory approvals from the FDA and DEA. Evidence from trials to date shows promising results, particularly with MDMA-assisted psychotherapy for PTSD and psilocybin for major depressive disorder. VA has been actively involved in psychedelic research and implementation planning. Challenges include resource constraints, staffing, training, and clinic redesign to accommodate the unique protocols required for psychedelic-assisted therapy. VA has also held a State-of-the-Art (SOTA) Conference on psychedelics and issued a request for applications (RFA) focused on testing MDMA and psilocybin for mental health conditions in Veterans. Additionally, a VA Psychedelic Assisted Treatment Integrated Project Team (IPT) is being established and is expected to launch in April 2024 to address research, clinical implementation, training, and evaluation strategies.

A recommendation was made to ask researchers involved in psychedelic research about their challenges in obtaining funding and accessing Schedule I controlled substances, as many are conducting studies independently without funding from ORD. This inquiry aims to understand their needs and difficulties to facilitate and support their work, potentially accelerating progress in this area. Dr. Smyth highlighted that during the State-of-the-Art (SOTA) conference, they engaged with researchers actively involved in psychedelic research. The conference included breakout sessions where researchers shared their challenges, particularly on the regulatory side. The outcome of the conference was a set of recommendations aimed at addressing these challenges and improving processes before further involvement in psychedelic research. Dr. Poropatich thanked Drs. Smyth and Schnurr for their contributions to advancing science, emphasizing how it underscores the importance of having internal VA expertise represented across various areas within the NRAC.

Prior to opening the public comment session, Dr. Poropatich took a moment to review potential recommendations from the NRAC. He summarized the discussion points and topics covered during the meeting, including collaborations with external partners, reaching underrepresented groups in VA research, forming subcommittees, such as the VA SHIELD subcommittee, addressing research topics like psychedelic-assisted therapy and toxic exposures, and specific interests from the Office of Research and Development (ORD). He then opened the floor for comments from the group on these topics.

Dr. Steven Dubinett suggested an additional focus area for the committee: exploring successful and impactful programs initiated by the VA. He highlighted the Lung Precision Oncology Program (LPOP) as an example, citing its significant impact in implementing screening for Veterans and reducing mortality rates. He emphasized the importance of studying successful programs to understand how they can be replicated in other clinical contexts for the benefit of Veterans and the nation. He underscored the unique position of VA as the only national health care system and emphasized the importance of leveraging this position for the benefit of Veterans and as a model for other health care systems. He also praised the funding model that covers both research and clinical implementation, emphasizing its effectiveness in addressing clinical problems and facilitating implementation science.

Dr. Ramoni emphasized the importance of marrying dissemination of known best practices, such as in lung cancer, with research, data collection, and community building. She highlighted two areas of nascent activity: Alzheimer's disease and related dementias, and traumatic brain injury, specifically in the realm of precision mental health. She stressed that advancement in these areas requires not only research funding but also clinical resources. She suggested that NRAC could play a role in advocating for support from undersecretaries and their departments to facilitate progress in these areas. Dr. Poropatich encouraged collaboration between the NRAC and other VA councils, such as the National Academic Affiliation Council chaired by Dr. Hildreth. He suggested that bringing these councils together for shared experiences could be beneficial, particularly if a face-to-face meeting becomes possible. Additionally, he highlighted the potential for new research themes arising from VA-DoD collaborations, citing the example of Fort Campbell, KY, opening its facilities to the local Veteran population. He invited comments or thoughts from the group on how to proceed, noting the establishment of the VA SHIELD and Biorepository subcommittees as a step forward. Dr. Kester suggested exploring areas of collaboration between VA and DoD research, identifying pain points, and highlighting successful collaborations as potential exemplars. Dr. Ramchand suggested the NRAC consider the impact of VA's shift into community care on Veterans' access to and quality of care. He believed that this shift presents an opportunity for valuable research, akin to a natural experiment. Additionally, he proposed exploring other access-related issues such as telehealth and alternative care delivery models. Dr. Ramoni emphasized the importance of broadening the scope of research to include health care services delivery questions alongside clinical research.

Dr. Laurencin expressed his concerns about the annual report on VA research, highlighting three main areas for improvement. Firstly, he suggested including a concise one or two-page executive summary outlining the major accomplishments of VA research in the past year. This summary should be easily understandable by laypersons, Congress, or the VA Secretary. Secondly, he emphasized the need to showcase how VA research translates into meaningful changes that benefit Veterans' lives. He proposed that the report should focus on important research findings and how these findings lead to improvements in care and services for Veterans. Lastly, he recommended incorporating a dashboard in the report to track the progress of major research projects and outline the goals and milestones. This dashboard would provide a dynamic overview of where VA research is heading and how it aligns with its objectives. Overall, Dr. Laurencin suggested

restructuring the annual report to prioritize clarity, impact, and goal-oriented tracking of research initiatives. Mr. Kuntz concurred with all of Dr. Laurencin's points.

Public Comment Period

Mr. Jester Jersey introduced himself as the son of a Veteran who served in the Navy for two decades, highlighting his family's personal connection to the issues discussed in the meeting. He described his father's service during the Vietnam conflict and Operation Desert Storm, followed by his stroke and subsequent need for care at home. Despite applying for benefits, Mr. Jersey's family faced challenges and delays in approval, particularly related to his father's exposure to Agent Orange and other service-related conditions.

He expressed gratitude for the passage of the Promise to Address Comprehensive Toxics (PACT) Act, which expanded eligibility criteria for benefits, allowing his family to refile previously denied claims and pursue additional ones. He emphasized the importance of research in addressing the health challenges faced by aging Veterans, especially those affected by service-incurred conditions. He stressed that research not only benefits Veterans but also helps their families navigate the complexities of caring for them. He shared his advocacy efforts, including speaking at the Research Advisory Committee on Gulf War Veterans' Illnesses, underscoring the importance of research on Veterans who served during various conflicts. He highlighted the need for research to focus on Veterans who served in multiple theaters of combat and those exposed to toxins, regardless of their service status or duration. Mr. Jester urged the Council to prioritize research efforts and outreach to ensure comprehensive support for Veterans and their families.

Dr. Susan Sisley, a primary care physician from Arizona, shared insights from her experience leading a nonprofit focused on Schedule I drug development trials. Her organization, the Scottsdale Research Institute, has conducted studies on cannabis for military Veterans with PTSD and explored the potential of various Schedule I drugs for pain management, PTSD, and opioid substitution. She emphasized the importance of VA research focusing on real-world drug development trials, particularly those involving natural substances like psilocybin mushrooms. She highlighted the institute's collaboration with the DEA to secure licenses for cultivating psilocybin mushrooms and cannabis for research purposes.

Regarding cannabis research, Dr. Sisley raised concerns about FDA-imposed clinical holds on Veteran cannabis studies, urging the VA to work with the FDA to address these barriers. She also underscored the need for research on natural psilocybin mushrooms, criticizing outdated perspectives within certain VA hospitals that hinder such studies. Furthermore, she discussed the potential for VA collaboration with states like Oregon and Colorado, which have decriminalized psychedelics and established patient registries for monitoring outcomes. She suggested leveraging opioid settlement funds available in various states, including Arizona, to support research on substance abuse treatment, particularly involving psychedelics. Finally, she encouraged VA to engage Native American Veterans and explore partnerships with tribal governments to access opioid

settlement funds for research purposes. She concluded by emphasizing the importance of expanding research efforts to address the complex health care needs of Veterans and advocating for collaboration between the VA and external stakeholders to advance this agenda.

Mr. Todd Scattini, a retired Army Lieutenant Colonel and West Point graduate, represented the American Legion's Blue Sky Lakeview Post #426, a virtual post with a membership spanning the country and beyond. He expressed gratitude toward VA's commitment to Veterans' well-being and commended its efforts to provide quality health care and support services. As a Veteran advocate and commander of the American Legion post, he emphasized the importance of increasing research into psychedelic medicines and plant-based treatments to address the challenges faced by Veterans and their families, including PTSD, chronic pain, addiction, and suicidal ideation. The American Legion has passed resolutions urging the VA to intensify research into psychedelic medicines, aligning with its previous advocacy for medical cannabis research. Mr. Scattini highlighted the potential of psychedelic medicines to revolutionize psychiatric treatment and urged the VA to lead this paradigm shift. Drawing attention to the collective responsibility to find solutions, he emphasized that Veterans, alongside other groups, represent the face of PTSD and underscored the need for effective treatment options. He urged the VA to leverage international partnerships, such as with Canada, which has legalized medical cannabis and provides access to plant-based medicines for Veterans.

Mr. Ray Brooks, a retired Marine Corps Lieutenant Colonel with extensive military and academic credentials, expressed gratitude to the VA and DoD for their service, emphasizing the importance of acknowledging their efforts in serving both Veterans and the broader public. He urged everyone to reflect on the collective pain and suffering experienced by all individuals, highlighting the need for effective programs and methods to bring genuine healing to society. He emphasized that VA serves as a starting point for healing, not only for Veterans but for the entire country, stressing that this is also a national security issue as adversaries observe how returning Veterans are rehabilitated. Drawing from his indigenous perspective as a Miskito Indian from Nicaragua, he advocated for integrating non-psychoactive substances and low-impact activities into the conversation about psychedelic-assisted therapy. He emphasized the positive impact of cannabis and the importance of considering alternative modalities for healing beyond substances that induce intoxication. Mr. Brooks underscored the need for discussions on these alternative modalities, aiming for healing without relying on substances that alter consciousness. He expressed readiness for engaged dialogue and reiterated the commitment of Veterans to serve the country for the greater good. In summary, Mr. Brooks emphasized the collective responsibility to address pain and suffering, while advocating for holistic approaches to healing. He expressed gratitude for the opportunity to engage in dialogue on these critical issues.

Ms. Emily Blair, a member of the Senate Veterans Affairs Committee, expressed appreciation for the insights provided during the meeting. She highlighted ongoing concerns regarding conflict-of-interest issues and indicated that they have been in communication with other research organizations on this matter. She expressed interest in learning more about whether Secretary McDonough prioritizes this issue and whether

further congressional action will be necessary.

Additionally, Ms. Blair echoed Dr. Laurencin's point regarding the need for the annual report to clearly demonstrate how research impacts Veterans' lives. She emphasized that clearer reporting would facilitate funding decisions at the congressional level. Ms. Blair also expressed concern about the apparent siloing of brain health research within ORD. She stressed the importance of prioritizing and properly carrying out brain health research for Veterans, noting that this is a topic of great importance to their leadership. The committee will continue to work with ORD to ensure that congressional intent is adhered to regarding this issue. In conclusion, Ms. Blair thanked NRAC for their ongoing work and expressed gratitude for the opportunity to participate in the meeting.

Dr. Poropatich expressed sincere appreciation to the members of the NRAC for their dedication and participation in the meetings. He specifically acknowledged Dr. Williams, Ms. Liza Catucci, and Rashelle Robinson for their invaluable support for the NRAC issues. He also thanked Drs. Ramoni, Tenhula, and Clancy for their support over the years. Additionally, Dr. Poropatich expressed gratitude for the quality of care and research provided by the VA, citing his personal experience at the Pittsburgh VA. He commended VA leadership for their innovative work, including psychedelic research, and expressed confidence in the future.

In conclusion, Dr. Poropatich thanked everyone for their active participation in caring for Veterans and their families, expressing best wishes to all.

Adjournment

Dr. Poropatich adjourned the meeting at 12:47 pm EST.

/s/ Ronald Poropatich, M.D., MS
Chairperson, NRAC
March 24, 2024