

**U.S. Department of Veterans Affairs
Office of Research and Development
Quarterly Meeting of the National Research Advisory Council (NRAC)
December 6, 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
Dr. Sanjay Doddamani

Committee Members Excused

Dr. Dallas Hack
Dr. Steven Dubinett

Speakers/Presenters

Dr. Ronald Poropatich, Chairman
Dr. Rachel Ramoni
Dr. George Lathrop
Dr. Wendy Tenhula
Dr. Molly Klote
Dr. Allison Williams, DFO
Dr. Marjorie Bowman
Dr. Matthew Kuntz

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 December 6, 2023. Dr. Allison Williams introduced herself as the new Designated Federal Officer (DFO), with Rashelle Robinson also present as alternate DFO. Dr. Ronald Poropatich, NRAC Chairman, officially called the meeting to order at 11:02 a.m. EST. Dr. Poropatich introduced the upcoming discussions, which included agenda review. The March 2024 meeting is set to be held in-person in Washington, DC. More details on the event followed.

Dr. Poropatich turned the meeting over to Dr. Rachel Ramoni, Chief Research and Development Officer (CRADO). Dr. Ramoni presented on the “Federal Advisory Committee *Subcommittee* Roles and Responsibilities”. She explained that prior to the subcommittee report out, the subcommittees are the working groups of any federal advisory committee. Their purpose is to prepare information for the NRAC to use to form recommendations. Activities may include:

- Gathering information
- Researching specific topics
- Analyzing relevant issues
- Drafting papers
- Reporting to the NRAC on subcommittee activities and findings

The NRAC is authorized to create subcommittees as needed. Subcommittees must be formally created and facilitated by the DFO. They may be comprised of NRAC and/or non-NRAC members with membership according to the expertise required. Members may be short-term or ongoing. Additionally, subcommittees do not directly advise the Secretary and do not work independently of the parent Federal Advisory Committee (FAC). Subcommittees must report their recommendations and advise to the full FAC at least annually. Dr. Ramoni concluded the presentation by providing a link to the Department of Veterans Affairs Federal Advisory Committee Management Guide, September 2023: [ACMO-GuideSep2023Final.pdf \(va.gov\)](#).

Dr. Poropatich thanked Dr. Ramoni for her presentation and asked the NRAC members to think of topics of relevance that could be used to form a new subcommittee. Dr. Poropatich then moved to the subcommittee annual updates, which included Sensitive Species and Diversity, Equity, and Inclusion (DEI). He first introduced Dr. George Lathrop, Jr, Chief Veterinary Medical Officer, to provide updates on “VA Sensitive Species Research Initiatives, the Five-Year Plan”.

Dr. Lathrop began discussing how they are well into their third year and entering the fourth year of the five-year plan. Remarkable progress has been made in the past year. The numbers of sensitive species animals used in VA research have fallen dramatically over the past 19 years and continues to be low. All tenets are being followed for the public law Sec. 247 PL117-103. In the past 12 months, they have answered four data calls for different members of Congress. Dr. Ramoni commented that reducing, replacing, and refining research involving sensitive species (feline, canine, and non-human primate) is of great interest to Congress and is mandated by law.

Dr. Lathrop then shared the current projects that have received VHA approval, and the final enhanced review process. The VA 5-Year Plan Key Features include:

- Canine, Feline, and Non-Human Primate (Sensitive Species) Research Protocols
- Education and Monitoring
 - Mandatory training provided by Chief Veterinary Medical Officer (CVMO) to all eligible Scientific Program managers and Principal Investigators.

- Alternative Methodologies
 - CVMO continues to work with the NIH Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) on position papers and utilizing alternative resources.

The following are the enhanced review and results from the Protocols for sensitive species submitted in 2021-2023:

- One reviewed did not meet newly established criteria.
- One is currently undergoing ethics review.
 - Client owned animal proposal.
- One was forwarded for Secretary VA Approval.
 - Approved in Felines.

Additionally, four projects are currently funded and underway, with results pending. This current year, one Letter of Intent (LOI) was received, and no new current protocols were funded. An Independent Review Panel was established in response to the mandate by Congress. They have contracted with a consulting company to review Sensitive Species Executive Committee Minutes and are preparing assessments. These consultants reviewed committee progress and decisions from the past 18 months, focusing on Congressional report content. They recently suggested requesting clarification of the requirement for the research to be combat-related.

Dr. Lathrop reviewed the progress of the action items in the plan submitted to Congress. There are externally-facing challenges involving computer simulation and gene chip modalities. Additionally, there have been interagency agreements and coordination with the Food and Drug Administration (FDA), United States Department of Agriculture (USDA), and the National Institutes of Health (NIH) on research and scientific integrity. They have also added language to the Federal Register and are asking for additional input.

Dr. Ramoni, the chair of the subcommittee, clarified that the same approval requirements are in place whether the animals are laboratory animals that must be sacrificed or companion animals that may benefit from the study. The sensitive species subcommittee recommended to NRAC that the approval requirements be less extensive in the case where companion animals may benefit from the research. The other recommendation, as Dr. Lathrop introduced, is a broad interpretation of combat related be used given the wide range of potential conditions that may be combat related.

Dr. Poropatich asked if the subcommittee has defined what the research requirements are for companion animals. Dr. Ramoni said the specific requirements for companion animals haven't been defined. In the extreme case, all the studies require secretary level approval in addition to other approvals and all the conditions must be combat related. On the other side, they would use the same approval processes that would be used for non-sensitive species to do the approval of

studies with companion animals. The subcommittee could develop a third process to recommend to the NRAC.

Dr. Poropatich recommended to have this topic discussed in the March meeting and to give the approval for the VA to pursue to the research requirements for companion animals. Dr. Ramoni will draft what they would see as the phrasing of the recommendation for NRAC to consider in the next meeting.

Dr. Poropatich introduced Dr. Molly Klote, Deputy CRADO, to present on the NRAC Diversity and Inclusion Subcommittee. Dr. Klote began by reviewing objectives. She discussed the Subcommittee that was established in 2020 on the recommendation of the NRAC to support COVID-19 therapeutic and vaccine trials. The Subcommittee had evolved to assist research teams in refining messaging, especially for underrepresented communities. Dr. Klote mentioned canceling meetings when there was no substantial agenda and presented a list of VA groups that participated in the committee. She highlighted the committee's achievements, such as recruiting 57,000 Veterans for COVID-19 trials and targeting new women into the Million Veteran Program (MVP) and the Patch network's prostate cancer study. The subcommittee is also helping with transgender data collection and messaging language in several studies.

Dr. Klote proposed considerations for the March meeting, questioning the ongoing necessity of the subcommittee, its composition, potential missing groups (e.g., rural Veterans), and its appropriate placement within ORD. The goal was to align the subcommittee's role with the preferences of the NRAC. Dr. Poropatich asked Dr. Klote what her thoughts on the Subcommittee are, given her experience. She identified an opportunity to enhance the marketing of the committee and leverage the existing talent. She included that improving the recruitment of women into studies aligns with the current focus of the FDA, and she emphasized the importance of obtaining recommendations not only from women but also from other communities underrepresented in drug development. She raised questions about effectively spreading the word, refining messaging, and addressing various aspects of trial participation, including decentralized clinical trials and childcare support during research appointments.

Dr. Poropatich asked the NRAC members to share their thoughts on the NRAC Diversity and Inclusion Subcommittee. Dr. Paula Schnurr raised a question about whether the committee should continue as an NRAC committee or if an alternative approach should be considered. Specifically, she mentioned existing ORD initiatives like the Women's Health Research Network and the work program aimed at enhancing the recruitment of women into VA cooperative studies. She pointed out potential concerns about duplication of efforts, particularly regarding women's recruitment, and emphasized the need for a broader focus on groups beyond women, such as rural Veterans. She inquired about the committee's alignment with existing efforts and suggested exploring the possibility of expanding the focus to address a wider range of demographic groups. Dr. Poropatich added that the efforts already being made are important and already structured into ORD, but questioned whether the work should be done as part of the NRAC subcommittee.

Dr. Ramoni concurred with Dr. Schnurr's comments and emphasized that there is robust support and interest in women's health and depending on the racial ethnic minority, there is still work to be done. She said that rural Veterans are an area that could use the advice of the NRAC and subcommittees. She believes that a subcommittee is a great venue to sort through systemic issues in a way that is transparent at the level that Congress and Veterans deserve. Dr. Poropatich requested that this discussion be continued at the March meeting and have the decision be made then. Dr. Rajeev Ramchand recommended in March to include as an addition to rural and women veterans, to consider LGBTQI+ communities. He explains that this topic is not specific to VA, but the field is grappling with certain issues related to gender and sexual identity that are important to discuss and consider.

Dr. Poropatich acknowledged the validity of the members' comments and emphasized the ongoing effort to assess the relevance of the NRAC and its potential positive impact on VA. He mentioned the presence of new members and the need to carefully consider the future of subcommittees, especially in light of changes in membership. He suggested that it would be premature to make a definitive decision at this point and proposed bringing the matter up for discussion and decision at the March meeting. He highlighted the importance of considering diversity and inclusion and expressed hesitation about prematurely closing the discussion. He invited additional comments from the NRAC before transitioning to the next topic.

Dr. Ramoni emphasized the limited capacity of receiving non-governmental advice within certain groups. She pointed out that non-governmental individuals in sensitive species groups, for instance, couldn't independently make formal recommendations to the Secretary. She suggested that if structural changes were being considered, having someone from the Subcommittee on the parent committee (or vice versa) could enhance integration. She highlighted the gatekeeping function of subcommittees and the NRAC, describing it as a requirement to receive outside input.

Dr. Poropatich welcomed Dr. Wendy Tenhula to provide an overview of "Hot Topics" from Congress and the White House. Dr. Tenhula began with an introduction of topics and aimed to share ideas that might be useful for additional conversation, alongside the strategic priorities and cross-cutting clinical priorities previously discussed. She mentioned that these themes, questions, or requests had originated from external stakeholders, including Congress and initiatives from the White House. The goal was to set the stage for meaningful discussions during the March meeting. While many of the topics were already reviewed prior to her presentation, she highlighted Precision Oncology which had not been discussed, and has generated increased interest from Congress.

Below is a list of topics of recent congressional interest in VA research:

- Research with Veterans living in rural areas
- Precision Oncology
- Collaboration with other federal agencies, universities, non-profits, etc.

- Data security and privacy
- Implementation of the Cleland-Dole/VA Infrastructure Powers Exceptional Research (VIPER) Act (e.g., Compensation for researchers from external sources)
- Mental health and suicide prevention research
 - Lethal means safety
 - Psychedelic assisted therapy
 - Hannan Act (precision brain health)
- Clinical trials (types, locations, # of Veterans)
- Million Veteran Program (MVP)
- Military Exposures/PACT Act
- Falls prevention
- Artificial Intelligence

The White House Initiatives Relevant to VA research are as follows:

- Cancer Moonshot
- Toxic Exposure Interagency Work Group/PACT Act Section 501
- Artificial Intelligence
- Mental Health Research
- Women's Health Research Initiative
- Scientific Integrity
- Open Data/Public Access

Dr. Poropatich inserted that there are numerous academic leaders on this committee and their expertise is invaluable. Dr. Hildreth from the Academic Affiliation Council will discuss more about VA and academic partnerships at the March meeting, which will cover many of the topics listed here. Dr. Rajeev Ramchand then spoke about his questions regarding how NRAC is best positioned to make substantial headway. He questioned whether the NRAC has the ability to influence whether VA dedicates resources to this area within fall prevention. Dr. Poropatich shared potential focus areas for the committee's discussions, including toxic exposures and collaboration with the Toxic Exposures Research Program (TERP) in conjunction with the Department of Defense (DoD). He also highlighted the importance of exploring partnerships between the VA and academia, specifically contributing to the efforts of Dr. Hildreth.

Additionally, he suggested investigating the role of medical marijuana in behavioral health treatment programs, considering its increasing legalization and usage among Veterans. He proposed limiting the discussion to three topics and welcomed input from committee members to determine the most meaningful and impactful areas for committee discussions.

Dr. Cato Laurencin emphasized the critical issue of Veteran homelessness, highlighting the statistic that 11-12% of Veterans become homeless. He expressed the need to shine a light on this issue and take meaningful actions to address it. He acknowledged the recognition and importance of this matter at the congressional and leadership levels. In contrast, he suggested that certain

topics, like fall prevention, may not require extensive attention, as fall prevention initiatives are already widespread in hospitals. He recommended the committee to prioritize impactful and relevant areas, such as Veteran homelessness and mental health and suicide prevention research.

Dr. Poropatich wrapped up this discussion with a request to include in the March meeting an updated summary of the Psychedelic Assisted Therapy Conference that met in September, homelessness discussion, VA academic partnerships, and more ways to bring the two committees together.

Dr. Poropatich then moved to introduce Dr. Marjorie Bowman, the Chief Academic Affiliations Officer at the Office of Academic Affiliations. She spoke on behalf of Dr. Carolyn Clancy, who could not be present at the meeting. Dr. Bowman extended appreciation to the committee for their invaluable service to Veterans and VA healthcare. She emphasized the committee's pivotal role in shaping the VA's research agenda, acknowledging the members' efforts in advancing VA research through recommendations and support. Specifically, she thanked the committee for advocating for conflict-of-interest rules in the recently passed Cleland-Dole Act, part of the Consolidated Appropriations Act of 2023, which addresses several challenges facing VA research.

Dr. Bowman proceeded to highlight key achievements and initiatives in 2023. Notably, she mentioned the Million Veteran Program (MVP) enrolling its millionth Veteran just days before Veterans Day, solidifying its position as the largest national genomic database in the United States. She emphasized the potential of MVP's vast dataset, connecting genomic, clinical, and lifestyle information to inspire future research and healthcare improvements.

Another significant accomplishment was VA's leadership role in exploring emerging therapies for mental health, particularly psychedelics. The Office of Research and Development (ORD) laid the groundwork for research studies on psychedelic-assisted therapy, recognizing the potential benefits for Veterans dealing with mental health conditions like post-traumatic stress disorder (PTSD) and depression. Additionally, ORD's evidence synthesis program conducted a critical review of the literature, and a state-of-the-art meeting on psychedelics was co-organized in September. Looking ahead to 2024, ORD is preparing to release a Request for Applications (RFA) to support research on psychedelic-assisted treatments for mental health conditions, focusing on the Veteran population.

Dr. Bowman also highlighted efforts related to health conditions linked to military exposures, particularly in support of the PACT Act. In this context, ORD began funding a study at the Nashville VA Medical Center to explore new technology for noninvasive detection of constrictive bronchiolitis (CB). CB is challenging to diagnose, and noninvasive diagnostic methods will significantly improve VA's ability to identify and provide care to Veterans with this condition.

Furthermore, ORD collaborated with the National Institutes of Health (NIH) on Project In-Depth, a five-year study designed to gain deeper insights into the chronic symptoms of Gulf War Illness (GWI). This collaborative effort reflects a commitment to advancing understanding and care for Veterans affected by Gulf War Illness.

Dr. Bowman also noted the significant growth of the Lung Precision Oncology Program (LPOP), an initiative that integrates clinical and research efforts to expand access to clinical trials and treatment. LPOP's unique hub-and-spoke model is intentionally designed to provide access to Veterans in rural and underserved areas, aligning with a broader push to have more trainees in these regions. LPOP may very well become an important prototype for clinical translation, one that can reduce the time between discovery and implementation for healthcare overall.

Collaboration is essential to addressing the complex issues that VA faces due to its rapidly changing environment and how VA stays focused on cross-cutting clinical priorities such as military exposures, PTSD, suicide prevention, traumatic brain injury, precision oncology, and pain in opioid use disorders. ORD has embarked upon major transformations that will change how it conducts business and better integrate its operations into the broader VHA enterprise. Significant headway has been made in 2023 in updating organizational structure and function and hiring critical staff members. Work on new and existing roles will continue into 2024 as ORD undertakes the transformation. Dr. Bowman shared Dr. Clancy's gratitude for the strong support from VA and VHA leadership and highlighted the privilege of being part of the nation's largest integrated healthcare system. She emphasized VA's role as an academic healthcare system, positioning it competitively against other research institutions. This transformation enables VA to engage in meaningful research impacting Veterans' lives. Dr. Bowman acknowledged that sustaining this effort requires significant cooperation and collaboration.

ORD strives to build processes and systems fostering collaboration between ORD and other parts of VHA, ensuring the delivery of impactful research that addresses Veterans' needs.

Incorporating feedback from end users and translating research into practice is a key focus, with collaboration not only benefiting Veterans but also reaching a global audience. Dr. Bowman cited examples such as the Cancer Moonshot, Mpox, and the COVID-19 response, showcasing the extraordinary collaboration seen in clinical trials.

The remarkable collaboration during the COVID-19 vaccine and therapeutics clinical trials was highlighted in a special issue of *Federal Practitioner* dedicated to VA's COVID-19 research response. The lessons learned from the pandemic, combined with future vision, aim to integrate VA research more comprehensively into the larger VA enterprise. This integration will expand access to research opportunities for Veterans and researchers, enhance visibility into research needs, and allow researchers to support clinicians in relevant areas, ultimately improving current and future care provided by VA. Dr. Poropatich thanked Dr. Bowman for presenting on behalf of Dr. Clancy and thanked them both for their hard work and contributions to VA. He recommended

dedicating 15–20 minutes to an overview of what the Academic Affiliation Council was doing for the NRAC during the March NRAC meeting.

Dr. Poropatich moved to the discussion to the NRAC Advisory Role and Support of ORD. Dr. Wendy Tenhula explained that part of the conversation that they are going to help facilitate with members is about how to move forward and be as productive as possible in using the time and expertise of the group. Dr. Sanjay Doddamani recommended setting additional time with Dr. Poropatich to have a focused discussion on the experiences and skill sets of the members, or on platform issues.

Dr Melinda Kibbe added that the NRAC doesn't just need report outs. They should be an advisory group discussing the difficult issues and giving the advice that is needed to impact change. She added that planning the March meeting only three months in advance will be a challenge.

Dr. Williams clarified that every member's appointment is valid for the March meeting. There will be reappointments during that time, or some will be moving off the council. She also suggested determining the length of the March meeting and the topics to be included, like the subcommittees and an overview of the NRAC responsibilities and role as an advisory committee. Dr. Poropatich officially confirmed March 6th as the meeting date and requested everyone's availability. He encouraged the group to confirm the agenda items in preparation.

Dr. Grant Huang, current ORD Deputy CRADO for Enterprise Optimization and former DFO, discussed how the recommendation of NRAC for ORD to establish a research response team played a crucial role in national efforts during the pandemic. This team not only conducted studies but also addressed the needs of VA staff. They encouraged people to explore the Federal Practitioner issue referenced by Dr. Bowman on behalf of Dr. Clancy, which showcased the activities and recommendations that stemmed from NRAC's guidance to address the pandemic. He expressed hope that this example serves as encouragement for all members, particularly newer ones, as discussions continue ways to move forward collaboratively.

Dr. Kuntz expressed a desire for regular presentations, perhaps annually, outlining the challenges and areas where ORD is struggling and seeking assistance. He cited examples from his time on the NRAC, where he was involved in addressing issues brought to their attention, such as those related to the Paperwork Reduction Act and funding concerns. He acknowledged that raising issues can be challenging, but it is crucial for addressing problems and finding solutions collaboratively. He mentioned specific challenges, such as the Vietnam Veterans Biorepository, and highlighted the importance of openly discussing areas where help is needed, such as Veterans' research in rural America, where there are qualified individuals, but other challenges exist. Dr. Poropatich requested that the members provide their top priorities.

Dr. Tenhula said that one area they are struggling in is the Air Force Health Study and the disposition of the data and specimens related to that study. She requested that this topic be included in the March meeting if there is time available on the agenda.

Dr. Poropatich suggest the March meeting be from 9am-3pm EST on March 6th, 2024, and requested the committee to be mindful and support the needs of the VA within the areas they believe they can contribute to. Dr. Williams will send a calendar hold.

Dr. Matthew Kuntz reviewed the NRAC recommended annual report targeted outcomes. The purpose was to modify targeted outcomes for research areas of high priority to ease understanding. He suggested three outcomes:

- Insights ready for implementation
- Generalizable knowledge to guide future research
- Insights requiring partnership external entities to move towards FDA approval

Public Comment Period:

Dr. Tom Zampieri expressed concern about delving too deeply into specific medical issue research problems during the March meeting, fearing it could lead to an extensive and potentially overwhelming discussion. He suggested focusing on broader topics, such as how VA can enhance collaboration with foundations, nonprofits, and universities, emphasizing the sharing of resources from a higher, 30,000-foot level view. He drew from his extensive experience in advocacy and testifying before Congress, highlighting the potential complexity of addressing massive programs like the Million Veterans Program.

Dr. Harold Hanson requested the status of the subcommittee evaluating VA Science and Health Initiative to Combat Infectious and Life-Threatening Diseases (VA SHIELD) as a repository system for the AFHS and Warren Collection. Dr Ramoni responded that there were several open questions remaining from the last meeting, like what is the current quality of the samples, and is there a suitable place within VA for the samples to be stored. Dr. Ramoni traveled to Los Angeles, CA and found there is not currently space to store those samples and they are involved in ongoing conversations with the Greater Los Angeles VA Medical Center. Another solution would be contracting for the storage of the samples with a reputable firm. Dr Poropatich recommended including this topic in the March meeting.

Dr. Ramoni concluded by reiterating her gratitude for the robust conversation and the participants' contributions, acknowledging the level of input based on their experience and expertise. She highlighted the critical next step, which involves gathering NRAC members' input on the topics they would like to explore during the upcoming in-person meeting. She proposed putting together a “menu” with brief descriptions and sharing it with NRAC members to align with their interests. Additionally, she mentioned the importance of understanding what pre-work would be helpful for the members to ensure a productive and focused conversation during the one-day meeting.

Next Meeting:

The next meeting of the NRAC will be held in-person on March 6th, 2024, from 9am to 3pm EST.

Action Items:

- Dr. Allison Williams will schedule the March 6th, 2024, NRAC Meeting and send out invites/holds via email.
- Onboard new NRAC members prior to the March meeting and provide roles, responsibilities, and calendar.
 - Have this in conjunction with the roles and functions of the NRAC.
- Draft agenda for the March NRAC meeting and seek out NRAC memberships' input on which topics will be deep-dive discussions.
 - Finalize the additional items for the March meeting, including a summary of the Psychedelics SOTA, Dr. Hildreth (NAAC Chair), and homelessness.
 - Invite Dr. Hildreth to March meeting and request Dr. Bowman to help facilitate.
- Sensitive Species Subcommittee will draft potential recommendations for the NRAC's consideration at the March meeting.
- Continue Diversity and Inclusion Subcommittee for now and set aside time in the March meeting to discuss and decide upon the future of the subcommittee.
- Draft a one-pager on the Air Force Health Study to be distributed to the NRAC to see if/how NRAC can engage and guide VA.

Adjournment:

The meeting was adjourned at 1:57pm ET.

DocuSigned by:
Ronald Poropatich
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Ronald Poropatich, MD, MS

Chairperson, NRAC