

**Department of Veterans Affairs
National Research Advisory Council Meeting
4th Floor, 811 Vermont Avenue, NW,
Washington, DC
October 30, 2024**

Minutes

Members Present

Ramchand, Rajeev, Chair
Hack, Dallas (virtual)
Husain, Fatima
Kester, Kent (virtual)
Kibbe, Melina (virtual)
Riddle, J. Dru
Rossiter, Alicia Gill
Zampieri, Thomas (virtual)
Zink, Caroline

VA Staff Present

Kabat, Margaret
Bever, Christopher
Catucci, Liza
Davey, Victoria
Griffin, Sarah
Hoffman, Stuart
Huang, Grant
Kilbourne, Amy
Krull, Holly
Ramoni, Rachel
Robinson, Rashelle
Roltsch, Mark (virtual)
Schulteis, Gerhard (virtual)
Small, Latonya
Smyth, Miriam
Tansey, Cassandra (virtual)
Tenhula, Wendy
Verna, Matt
Williams, Allison
Wynne, Marc

Guests

Alcazar, Vince
Mendietta, Shelly
Stout, Elizabeth

Call to Order - Allison Williams, ND, PhD, RN, DFO

Dr. Williams called the meeting to order at 8:35 a.m.

Introductions - Rajeev Ramchand, PhD, Chair

The members, VA staff, and other attendees introduced themselves. Chair Ramchand introduced himself as the new Chair of the Council.

Office of Research and Development Update - Rachel Ramoni, PhD, CRADO

Dr. Ramoni recognized the consequentiality of NRAC meetings on the Office of Research and Development's (ORD's) work. The collaboration of ORD and the RAND Corporation following the previous in-person NRAC meeting formed the VA's response to the COVID-19 pandemic. She also acknowledged Dr. Grant Huang who received a prestigious award at the previous Association of Military Surgeons of the United States (AMSUS) meeting.

ORD does not have an FY 2025 budget yet, but it anticipates a 62 million-dollar decrease from 2024. ORD has moved toward organizing VA research into broad portfolios and specific actively managed portfolios (AMPs) that reflect areas of Veteran need. The new portfolio structure formally went into effect on October 1, 2024, and includes the AMP on Traumatic Brain Injury (TBI), led by Stuart Hoffman.

The 100-year anniversary of ORD is approaching, with a half day of celebration planned for May 13, 2025, led by Deputy Chief Research and Development Officer (CRADO) for Strategy, Partnership, Outreach and Communication (SPOC), Marc Wynne.

Administration Transition - Marc Wynne, Deputy CRADO

Mr. Wynne highlighted the five central concerns in an administrative transition: (1) to ensure continuity of government in a seamless and peaceful transfer, (2) to prepare for the upcoming administration, (3) to facilitate the vetting and appointing of officials, (4) to promote national security and stability, and (5) to engage with stakeholders.

Mr. Wynne discussed traditional timelines during the power transfer for the presidential candidate, the VA, and Congress. He highlighted several key dates for the rest of 2024 and early 2025, including the beginning date of briefings for landing teams, the date the new Congress is seated, the date committee assignments begin, and the date of the Senate confirmation process. The Kamala Harris campaign is reportedly further ahead on the processes of filing the Memorandum of Understanding, ethics pledge and financial documents than the Donald Trump campaign. Thus, a Donald Trump campaign victory may put the Department of Veterans Affairs behind schedule compared to the typical timelines.

The ORD has developed a 100-day plan and is preparing a series of congressional briefings regarding key areas of research including suicide prevention, military exposure, and brain health.

Remarks from the Chief of Staff - Margaret Kabat, Chief of Staff

On behalf of the Secretary, Chief of Staff Margaret Kabat extended thanks to the NRAC and recognized their importance. She discussed her experience interfacing with veteran health research and the importance of that research in informing VA initiatives. She also spoke on her work regarding veteran homelessness in Los Angeles, which has the largest population of homeless veterans.

Subcommittee Updates - Allison Williams, ND, PhD, RN, DFO

Dr. Williams introduced the subcommittee update portion of the meeting, which featured three updates headed by Veteran Affairs staff and a new proposal.

Update on Sensitive Research Subcommittee - Cassandra Tansey, DVM

The Sensitive Species Subcommittee's FY 2025 goals are to meet and complete the goals of the ORD's five-year plan for the subcommittee and to request a legal amendment from Congress that would allow it to conduct some sensitive species research. The sensitive species in question are canines, felines, and non-human primates (NHPs).

Public Law 116-94, Section 249 from 2019 required the VA to reduce or eliminate sensitive species research. ORD had developed a five-year plan to meet this goal, to be enacted from 2020 through 2025. The subcommittee's work since 2020 resulted in the finalization or closure of sensitive species research in three canine projects, four feline projects, and three NHP projects. There are five currently approved projects with sensitive species; three in canines and two in NHPs. Data collection is complete in two of the canine studies and the remaining study utilizes pet dogs who are being treated for a naturally-occurring cancer.

Although plain reading Section 247 of the Consolidated Appropriations Act 2024 requires elimination of animal research at the VA by 2026, the OGC reported that an alternative interpretation of the legislation would mean the VA only needs to begin implementing a plan for reduction by that time. The alternative interpretation risks a purpose statute violation if VA auditors find the less restrictive reading of the section is wrong. Research funding for projects involving sensitive species must be approved by the Secretary of the VA (SecVA). In FY 2025, ORD will propose legislation that clarifies and expands the language with which the SecVA can submit waivers for legal prohibitions on sensitive species research.

Update on Air Force Health Study and Warren Collection New Subcommittee - Victoria Davey, PhD

The Air Force Health Study and Warren Collection Subcommittee was established in FY 2024 in order to oversee Air Force health studies and the Warren Collection (WC), which is a collection of 48 thousand serum specimens from 9,000 airmen in the Vietnam War who had Group A *streptococcus* infections. The specimens were archived in Air Force custody and the data have been stored at the National Academies of Science, Engineering, and Medicine (NASSEM). The ORD intends to transfer the specimens to its biorepository system, VA SHIELD.

The subcommittee has already met its 2024 goals to determine if VA SHIELD was ready to handle the specimens, whether the ORD should accept the WC, and what testing of integrity should be done on the specimens prior to VA accepting custody. There was an affirmative finding to all three of those goals. The new active objectives in 2025 were (1) to advise ORD on research project selection strategies, (2) to review and advise upon the progress of research regarding the samples, and (3) to determine the ongoing usefulness and lifespan of the subcommittee. By the end of the year, the subcommittee lead is to follow-up with the DFO Administrators with a charter, membership list, and meeting dates.

Update on Diversity and Inclusion Subcommittee - Mark Roltsch, PhD

The Diversity and Inclusion Subcommittee's purpose was to ensure a diverse population of study in COVID-19 trials conducted by the VA. It also assisted the Women's Recruitment Campaign for the Million Veteran Program and the PATCH Network in their individual programs. Dr. Roltsch reported that the subcommittee had met its goals, and he recommended the closure of the subcommittee.

The ORD Diversity, Equity, and Inclusion (DEI) Work Group is a different committee within the ORD whose goals and operations are separate and unrelated to NRAC's subcommittee. The work of this committee will continue within ORD.

Dr. Catherine Zink moved to close the subcommittee, and the motion was seconded by Dr. Alicia Rossiter and passed unanimously.

Update on FY 2024 NRAC Recommendations - Marc Wynne, Deputy CRADO

Mr. Wynne presented on the topic of USC 18 § 208, Conflict of Interest (COI). The VA has a unique public-private relationship with researchers in that most VA researchers are appointed both by the VA and by an academic or nonprofit organization, also known as dually appointed. Dually appointed researchers are subject to federal COI statutes. Under the new Office of Government Ethics (OGE) interpretation, conducting business and conducting science must be seen as a single matter, resulting in the necessity of a waiver for a dually appointed physician to conduct research that impacts both VA and the academic or nonprofit organizations with which VA researchers work. ORD anticipated thousands of waivers per year.

The Office of General Counsel (OGC) submitted concerns about the waiver volume and the impact it would have on slowing down VA research operations to Congress, but the OGE returned a decision that disagreed. OGC will meet with OGE to discuss possible solutions, and ORD expressed that it would like to be a part of those discussions. Additionally, OGE had wanted to make the waivers publicly accessible, which would cause an issue for researchers, as that research was considered proprietary, and it would also be accessible to unfriendly nations. ORD hoped OGC would push back against this request.

NRAC will have an anticipated window between February and March to submit legislative recommendations for these issues following the appointment of a new Secretary.

Research Affiliation Agreements - Gerhard Schulteis, MD, Special Advisor, Field Operations, ORD

Dr. Schulteis stated that the ORD and OAA policy as currently written has limitations on which trainees can conduct VA research. Currently only trainees from VA-sponsored training programs, or from affiliated Health Professions Training Programs Trainees can conduct VA research in satisfaction of their training requirements. 38 USC § 7302 and 7303 allow for a broader scope of affiliations for research and education purposes, but the Office of Academic Affiliations (OAA) has limited its policies presently to cover Health Professions Trainees (HPTs), and any research that might be part of their training program. To allow for trainees from non-HPT programs of critical relevance to the VA research mission (e.g. Public Health, Engineering, Informatics/Information Sciences, etc), ORD and OAA have proposed that ORD issue its own policy and research affiliation agreement template to cover research-specific training at VA for trainees from affiliated programs.

The NRAC Subcommittee responding to the GAO report on VA-Nonprofit Corporation-Academic Affiliate relationships noted that certain VAMCs are remote from their current HPT academic affiliates (AAs) such that dually appointed research faculty would be unable to receive the intended collaborative benefits between a VAMC and an AA facility. These stations could also benefit from ORD-issued research-specific affiliation agreement policy to create affiliations with more proximal institutions with training programs in relevant disciplines. For that reason, the ORD intends to develop and oversee an expanded Policy and Affiliation agreement with help from the OAA that will allow for research-specific training programs for non-HPTs.

Proposal of VA Research and Emerging Health System Priorities Subcommittee - Amy Kilbourne, PhD, MPH

The purpose of the proposed subcommittee would be to determine and advise the ORD in how to support novel research and evaluation to directly address VA health system needs. Dr. Kilbourne noted that the growing cost of healthcare within veteran populations over time would cause challenges for VA leadership, and she proposed that the new subcommittee would be a solution because it could advise the ORD and other VA branches on optimized research to understand and propose solutions to managing healthcare costs in order to inform VA policy and efficiency interventions.

Dr. Kilbourne cited her experience running evaluations within the Quality Enhancement Research Initiative (QUERI) of VA's Health Systems Research (HSR) branch as an impetus for this proposal. She reminded the Council of the existence of the Evidence-based Policy Subcommittee (EBPS) that was established to superintend health system evaluations in response to the Evidence Act (US PL 115-435) and is managed by QUERI. Organizationally the EBPS is under VHA Operations in the Chief Strategy Office's Strategic Directions Committee and, while this Subcommittee has reporting lines to the VHA Governance Board, a complementary Subcommittee within NRAC would enable external input on optimizing analyses pertaining to health system research and evaluation efforts and stronger communication channels with the SecVA.

Chair Ramchand moved to establish the subcommittee, and Dr. Dru Riddle seconded the motion, which passed unanimously.

FY 2024 Annual Assessment of Activities and FY 2025 Operations Plan - Allison Williams, ND, PhD, RN, DFO

Dr. Williams first presented on the FY 2024 Assessment of activities. There were three total NRAC meetings in calendar year 2024. In 2024, the ORD fully met their goal to submit one recommendation to the SecVA regarding a change to the interpretation and implementation of 18 U.S.C. § 208 (COI) with respect to research as discussed at the March 6, 2024, NRAC meeting. The SecVA approved the recommendation, and it is in progress. NRAC also met their goal of facilitating senior Veterans Affairs leadership participation in its meetings, including hosting Dr. Carolyn Clancy, Assistant Undersecretary for Discovery, Education, and Affiliate Networks of the Veterans Health Administration (VHA) at the two previous meetings and Ms. Margaret Kabat, Chief of Staff, earlier at this meeting.

Dr. Williams then presented on the 2025 operations plan. ORD's goals for NRAC in 2025 include providing recommendations to the newly incoming Secretary of Veterans Affairs, advising on the progress of VA's Research Enterprise Transformation, and continuing to

oversee the plan for reduction/elimination of sensitive species animal studies. NRAC will also advise on VA's actively managed portfolios. There are four proposed committee meetings for calendar year 2025, all of which are proposed to be either virtual or hybrid.

Public Comments

Dr. Williams shared that in advance of the meeting, the NRAC DFO's received 125 letters requesting that the VA expand the Air Force Health Study Charter to include veterans of aviation regardless of service history or expand the scope of veteran aviator cancer research. She presented the content of the letters to NRAC including the purpose, request and supporting information cited. Specifically, the letter noted that three studies had been published from 2021 to 2024 with total sample sizes in the hundreds of thousands, finding elevated cancer rates in military aviators.

Dr. Williams introduced two guest speakers. The first commenter was retired Colonel Vince Alcazar, representing the Military Aviator Coalition for Health (MACH), which he founded. He presented the aforementioned findings to NRAC as a matter of awareness and called upon NRAC to use the findings to conduct and further their own research. He suggested the creation of a new subcommittee as one possible action.

The second commenter was retired Colonel Shelly Mendieta of the 39th Air Base Wing, Incirlik Air Base, Turkey. She spoke of her personal experience flying in combat missions in Iraq and Afghanistan and her subsequent breast cancer diagnosis. Some aviators who sought mammograms as a result of Colonel Mendieta sharing her experiences discovered that their treatment could not be covered by the Honoring our Promise to Address Comprehensive Toxics Act (PACT Act) if their cancers were not deemed service-related.

Colonel Mendieta called on the VA and NRAC to expand their research to benefit aviating veterans because the three relevant studies did not yet conclusively link the increased cancer rates to the act of flying military aircraft.

Final Comments and Adjourn - Rajeev Ramchand, PhD, Chair

Chair Ramchand invited final comments. Dr. Ramoni offered a comment inspired by the public comment session. She said that the deadliest cancer among Veterans Affairs is lung cancer, and that one of the Research and Development Office projects is to identify whether people with a history of military exposures should have different lung cancer screening guidelines than the rest of the population and to pass those developed findings to a U.S. Preventative Services Task Force.

Dr. Williams extended thanks to the NRAC members, public attendees, and Department staff in attendance as well as the transcriber. On a motion duly made and seconded, Chair Ramchand adjourned the meeting at 2:52 p.m.

/s/Rajeev Ramchand
Committee Chair
Date: January 2, 2025

/s/Allison Williams, ND, PhD, RN
Committee Designated Federal Officer

