Research Advisory Committee on Gulf War Veterans' Illnesses

Committee Meeting Minutes

February 8–9, 2023

Oahu Veterans Center

Oahu, Hawaii

I hereby certify the following minutes as being an accurate record of what transpired at the February 8–9, 2023 meeting of the Research Advisory Committee on Gulf War Veterans' Illnesses.

KAREN BLOCK

Digitally signed by KAREN BLOCK
Date: 2023.03.28 13:59:25 -04'00'

Karen Block, Ph.D.
Designated Federal Officer
Research Advisory Committee on Gulf War Veterans' Illnesses

Cheryl Lyn Walker, PhD

Digitally signed by Cheryl Lyn Walker, PhD
Date: 2023.04.13 13:55:13 -05'00'

Cheryl Walker, Ph.D.
Chair
Research Advisory Committee on Gulf War Veterans' Illnesses

Attendance Record	
Members of the Committee:	**Invited Speakers:**
Dr. Cheryl Walker, Chair	Karen Block, PhD
Dr. Kenneth Ramos, Vice-chair	Mr. Ronald Brown
Dr. James Baraniuk	Jean-Paul Chretien, MD, PhD - cancelled
Mr. Ronald Brown	Steven Jones, MPH
Retired Col. Richard Gaard	Molly Klote, MD, CIP
Dr. Drew Helmer	Mr. Kirt Love
Mr. Thomas Mathers	Jacob Lindheimer, III, PhD
Ms. Delphine Metcalf-Foster	Sumitra Muralidhar, PhD
Ms. Sonya Smith	LaTonya Small, PhD
Dr. Elaine Symanski	Ms. Sonya Smith
Ms. Jane Wasvick	Thomas Thomou, PhD - cancelled
Ms. Barbara Ward	Marc Williams, H.D., PhD, Fellow AAAAI. Note:
Mr. William Watts	presenter changed to Karen Block, Ph.D
Dr. James Woody	
Members Absent:	
Mr. Brent Casey	
Designated Federal Officer (DFO):	
Dr. Karen Block	
Alternate DFO (Alt-DFO):	**Institute for Learning, Education and Development (ILEAD)**
Marsha Turner	
	Kenneth Powell
Committee Staff:	
Mr. Stanley Corpus	**Attendance:**
Mr. Daniel Sloper	**February 8**
	In Person: 0
	Online via Webex: 65
RACGWVI Subcommittee Members:	Subtotal: 65
Dr. Cheryl Walker, Chair	
Dr. Kenneth Ramos, Vice-chair	**February 9**
Dr. Karen Block	In Person: 2
Mr. Ronald Brown	Online via Webex: 62
Dr. Drew Helmer	Subtotal: 64
Ms. Delphine Metcalf-Foster	
Mr. William Watts	**Two Day Total = 129**

Meeting of the Research Advisory Committee on Gulf War Veterans' Illnesses (RACGWVI)
Department of Veterans Affairs

FEBRUARY 8, 2023 9:00am – 3:00pm Hawaii Standard Time (HST) (2:00pm - 8:00pm ET)		
9:00am HST (2:00pm ET)	Business	
9:00-9:30am HST (2:00-2:30pm ET)	**Welcome, Committee Introductions and Shared Vision**	**Cheryl Walker, PhD** RACGWVI Chair **Dr. Kenneth Ramos, MD, PhD** RACGWVI Vice-Chair
9:30-9:50am HST (2:30-2:50pm ET)	**FACA 101 Training**	**LaTonya Small, PhD** Program Specialist, Advisory Committee Management Office (ACMO)
9:50-10:20am HST (2:50-3:20pm ET)	**VA Gulf War Research Program**	**Karen Block, PhD** Senior Program Manager Gulf War Research VHA Office of Research & Development (ORD)
10:20-10:50am HST (3:20-3:50pm ET)	**Intergenerational Effects of Military Exposures Work Group**	**Marc Williams, H.D., PhD, Fellow AAAAI** Toxicology Directorate, Health Effects Division US Army Public Health Center
10:50-11:00am HST (3:50-4:00pm ET)	Break (10 min)	
11:00am-12:00n HST (4:00-5:00pm ET)	**Department of Defense - Defense Advanced Research Projects Agency (DARPA): Biological Technologies - cancelled**	**Jean-Paul Chretien, MD, PhD** Commander, Medical Corps, US Navy Program Manager Biological Technologies Office, DARPA **Thomas Thomou, PhD** Senior Scientist & Engineer DARPA
12:00-1:00pm HST (5:00-6:00pm ET)	**Individual Longitudinal Exposure Record (ILER) Update and Wearable Capabilities to Assess Military Exposures**	**Steven Jones, MPH** Director, Force Readiness and Health Assurance Policy, Office of the Deputy Assistant Secretary of Defense for Health Readiness Policy & Oversight
1:00-1:45pm HST (6:00-6:45pm ET)	Lunch (45 min)	
1:45-2:30pm HST (6:45-7:30pm ET)	**Committee Discussion**	
2:30-3:00pm HST (7:30-8:00pm ET)	**Public Comment**	**Visitors and Invited Guests**
3:00pm HST (8:00pm ET)	Adjourn	DFO/Committee Chair

FEBRUARY 9, 2023 9:00am – 12:30pm HST (2:00pm - 5:30pm ET)		
9:00am HST (2:00pm ET)	Business	
9:00-9:05am HST (2:00-2:05pm ET)	**Welcome / Opening Remarks**	**Kenneth Ramos, MD, PhD**
9:05-9:35am HST (2:05-2:35pm ET)	**Million Veteran Program (MVP) Overview**	**Sumitra Muralidhar, PhD** Director, Million Veteran Program VA Office of Research and Development
9:35-10:00am HST (2:35-3:00pm ET)	**VA Research Processes and Protections**	**Molly Klote, MD, CIP** Director, Research Protections, Policy & Education Deputy Chief Research and Development Officer - Enterprise Support VA Office of Research and Development
10:00-10:15am HST (3:00-3:15pm ET)	**Veteran Perspective: 1990-91 Military Exposures**	**Mr. Ronald Brown** 1990-91 Gulf War Veteran
10:15-10:30am HST (3:15-3:30pm ET)	**Veteran Perspective: Gulf War Research Historical Perspective**	**Mr. Kirt Love** 1990-91 Gulf War Veteran
10:30-11:00am HST (3:30-4:00pm ET)	**Veteran Perspectives: Military Exposures Roundtable Discussion**	**Mr. Ronald Brown** **Col. Richard Gaard** **Mr. Kirt Love** **Mr. Tom Mathers** **Ms. Delphine Metcalf-Foster** **Ms. Sonya Smith** **Mr. Bill Watts** **Dr. James Woody (Chair)** Veterans of Operation Desert Shield/Desert Storm
11:00-11:15am HST (4:00-4:15pm ET)	Break (15 min)	
11:15-11:35am HST (4:15-4:35pm ET)	**Acute exercise tolerance among Veterans with Gulf War Illness**	**Jacob Lindheimer, III, PhD** Deputy Associate Chief of Staff/Research William S Middleton VAMC, Madison, WI
11:35am-12n HST (4:35-5:00pm ET)	**Committee Discussion**	
12n-12:30pm HST (5:00-5:30pm ET)	**Public Comment**	**Visitors and Invited Guests**
12:30pm HST (5:30pm ET)	**Adjourn**	**DFO/Committee Chair**

Committee Meeting Minutes

This meeting follows a subcommittee Veteran Engagement Session held on Feb 7, 2023.

Welcome, Introductions and Opening Remarks

— Cheryl Walker, Ph.D., RACGWVI Chair

Dr. Walker welcomed and thanked everyone for joining the first meeting of the RACGWVI in Hawaii. She then asked Dr. Block to give the committee its charge.

Welcome and Opening Remarks

— Karen Block, Ph.D., VA Office of Research & Development and Designated Federal Officer, RACGWVI

Dr. Block, RACGWVI Designated Federal Officer (DFO) and Director of the Office of Research and Development (ORD) Gulf War Research Program in Washington, D.C. Stated this was a public meeting of the VA chartered RACGWVI. She thanked all participants for joining the meeting either in person or via Webex.

She noted the meeting - was posted in the Federal Register, would be chaired by Dr. Cheryl Walker and vice-chair Dr. Ken Ramos, and met the required member quorum. The meeting was recorded and with written consent, all materials would be publicly posted following the meeting. Anyone not speaking should mute their microphones. There would be time for public comments at the end of the meeting. Questions/comments could be submitted in advance via the chat or email. Dr. Block returned control of the meeting to Dr. Cheryl Walker.

Session 1: FACA 101 Training

— LaTonya Small, PhD

Program Specialist, Advisory Committee Management Office (ACMO). Dr. Small presented the committee with their annual Federal Advisory Committee Act (FACA) training for 2023.

This training included the definition of FACA, when FACA applies and Federal Advisory Committees (FACs) requirements. Additionally, Dr. Small discussed the rules and regulations that all FACs and each member of a FAC must follow, where, when, and how those rules and regulations are applied and FAC best practices.

Session 2: VA Gulf War Research Program Update

— Karen Block, PhD

Senior Program Manager Gulf War Research Veterans Health Administration (VHA) Office of Research & Development (ORD)

Dr. Block introduced herself. Besides being the DFO for the RACGWVI she is also the director of the ORD Gulf War Illness research program in Washington, D.C. The focus of her presentation was an update on VA research projects, academic partnerships and Veteran outreach and education.

The VA has conducted research studies and advanced the level of healthcare for 90 years.

The VA serves nine million Veterans per year; has partnership with over 90% of U.S. Medical Schools, with 75% of physicians receive some training or experience at VA, and 44,000 students per year rotate through a VA facility.

The VA has two complementary offices to generate evidence and inform policy on Gulf War (GW) and military exposures health outcomes; Health Outcomes Military Exposures (HOME) lead for section 509 of PACT Act; ORD lead for section 501 of PACT Act. HOME's mission is to maintain exposure registries, monitor scientific literature and trends in VA benefit claims data, and track Veteran health outcomes, manage three War Related Illness and Injury Study Centers (WRIISCs) and manage/support airborne hazards/burn pits and toxic embedded fragments centers. ORD's

mission is to fund peer-reviewed research conducted by VA investigators and support VA research infrastructure.
Dr. Block addressed the Gulf War Illness (GWI) research efforts that resulted from a variety of new illnesses reported by U.S. Military personnel that were the result of exposure to multiple and varied toxic conditions during the 1990-91 Gulf War.
Dr. Block presented a timeline chronicling the evolution of GWI and GWI-research, which included both VA and Department of Defense (DOD) research centers and reports, starting with the 1990-91 Gulf War to current day. Despite the years of integrated and extensive research projects resulting in a better understanding of possible causes of GWI, there has been little progress in developing treatments. That is not the fault of the researchers, but due to the complexity of the disease, the difficulty in creating laboratory experiments and models based on the original causal exposures and how GWI is a complex multi-symptom illness affecting both brain/neurological and body/physiological function. Present treatments target symptoms affecting quality of life; those treatments include nutraceuticals (i.e., anti-inflammatories, antioxidants, probiotics) and mindfulness (i.e., yoga, tai chi, piscatorial).
Dr. Block reviewed the VA-ORD Gulf War Research budget and research (laboratory and clinical) project funding.
Dr. Block presented the VA & NIH (National Institutes of Health) collaborative interagency effort called Project IN-DEPTH (**In**vestigative **De**ep **P**heno**t**yping Study of Gulf War Veteran **H**ealth). The study focus is to phenotype and compare Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) and GWI. The project has four goals: Recruit; Deep Phenotyping of GWI and Healthy Veteran Controls; Secondary/Meta-analysis between cohorts; Develop Resources for future evidence-based research. Primary analysis will look at immunological, bioenergetic and homeostatic regulatory parameters. Secondary analysis will be a meta-analysis looking at the GWV with GWI population and compare it to the civilian study groups with ME/CFS. At the time of the presentation the study was actively recruiting participants.

Committee Questions and Discussion:
Tom Mathers: Has project IN-DEPTH considered adding Long-COVID to its deep phenotyping study and is it possible to do a control instead of a meta-analysis versus other conditions?
Dr. Block: No, not as part of the IN-DEPTH study. The NIH has their own study looking at CFS and COVID/Long-COVID.
Cheryl Walker: What bio assessments are going to be part of the repository?
Dr. Block: The list is extensive, but will include blood, cheek swabs, DNA, and other samples. A full list can be provided.
Male GWV: Asks why he is not contacted to be part of clinical studies, and how can Veterans be contacted to be part of the study?
Karen Block: Each study varies based on geographic location, inclusion and exclusion criteria and recruitment standards/protocols approved by an Institutional Review Board (IRB). Those criteria affect how people are selected for a study. Currently the VA is establishing a research resource for any person who is interested in being part of a research study.
James Baraniuk: Is there a mechanism or procedure that a non-VA clinical researcher can follow that will allow them to post clinical research opportunities inside a VA facility?
Karen Block: That is an individual VA facility determination.
Female GWV: Described her experiences with adverse immune reactions to vaccines, living in military bases containing asbestos and possibly other toxic chemicals/compounds, exposure to burn pits and other toxins while serving in the desert. Currently seeing VA doctors for hematological disorders. She asks if the VA can establish specialized clinics to deal with GWV with GWI/GW-toxicological disorders?

Karen Block: Informed the GVW that there were currently no hematological clinical studies being conducted by the VA. She also suggested the GWV contact the War Related Injury and Illness Study Center (WRIISC) as they may be able to help her.
Ron Brown: Supported Dr. Baraniak's comment about allowing non-VA clinical researchers to recruit inside the VA for GWI-related clinical studies.
Tom Mathers: Emphasized the point that non-VA clinical researchers should be able to advertise at the VA, and the RACGWVI should investigate how it could facilitate that process.
Cheryl Walker: That topic will be addressed in the committee discussion to include possibly starting a subcommittee to investigate such a process.

Session 3: Intergenerational Effects of Military Exposures Work Group.
— Marc Williams, H.D., PhD, Fellow AAAAI Toxicology Directorate, Health Effects Division, US Army Public Health Center
Due to unexpected circumstances Dr. Williams was unable to present. Dr. Karen Block, Work Group Co-Chair, presented on his behalf. Dr. Williams was able to participate in the discussion.
An Intergenerational Effects of Military Exposures Work Group (IEMEWG) was convened by the VA to assess the feasibility and achievability of a comprehensive Health Monitoring Research Program (HMRP) as outlined by the National Academies of Science, Engineering, and Medicine (NASEM), Gulf War & Health Volume 11; Generational Health Effects of Serving in the Gulf War and in response to Public Law (PL) 114-315 . Under findings and recommendations, NASEM found 27 chemicals of interest associated with military service that could induce in either men or women reproductive, birth or developmental health effects. Those chemicals were categorized as deployment-related exposures, pesticides, combustion products and fuels and solvents. In conclusion, the NASEM review did not find evidence of a causal association or limited suggestive association between exposure and reproductive or developmental effects linked to health effects in the Gulf War and Operation Iraqi/Freedom/Operation Enduring Freedom (OIF/OEF) military service member populations. Conclusions need to be interpreted within the broader context of both the Veterans' and their progeny and all exposures over the course of their life starting in utero. Those exposures, (i.e., nutritional, environmental) can affect a person's genome or epigenome.
The NASEM report recommended the VA establish a comprehensive Health Monitoring Research Program (HMRP). The objective of the HMRP would be to determine if Veterans' descendants are at risk for health effects caused by parental military exposures. The program would have three arms: Monitor the Veteran and progeny; collect data; conduct research. The VA established an IEMEWG to determine the feasibility and achievability of the HMRP. The group contained subject matter experts (SME) from VA, DOD, NIH, Center for Disease Control and Prevention (CDC), Health Resources & Services Administrations (HRSA) and input from academia and Veterans. The group studied the feasibility and challenges of the project and established a set of basic considerations. Enrollment and recruitment were a significant challenge. The group leveraged the study using existing programs and activities (e.g., Million Veteran Program, DOD serum repository) helping to save costs and accessing already engaged study populations. If the HMRP is determined to be feasible, additional requirements from PL 114-315 will be triggered, including the creation of a VA Federal Advisory Committee to oversee the research and a prohibition against VA participating in the research. Due to insufficient scientific evidence and multiple barriers to include feasibility, the final conclusion was the IEMEWG did not support the creation of HMRP.

Committee Questions and Discussion:
Ron Brown: How come the VA doesn't reach out to GWV families/groups who are collecting birth defect information?
Karen Block: The IEMEWG did contact those groups and included their information as part of their study.
Ken Ramos: As a member of that committee, when the committee put forth the recommendations they were based on an ideal situation, however, the reality was that the scale of the project wasn't feasible. The new question that should be asked is can that large study be scaled down to a smaller, cost-effective research study.
Drew Helmer: Agrees with Dr. Ramos, that based on recent scientific evidence intergenerational effects needs to be studied.
Karen Block: Emphasized that she agreed that the research is important and needs to be done. However, due to the wording of PL 114-315, if enacted the VA would have been pushed out and not allowed to be part of the research project.
Tom Mathers: Agreed that a study of the original purposed scale would have been difficult to perform. Also, the information put out by the various groups needed to be vetted for accuracy and scientific merit. Regarding the 27 toxicants, from the presentation it sounds like there were no potential associations.
Mark Williams: There were no causality relationship in those 27 toxicants, but there were different levels of association.
Karen Block: None of the scientific publications showed causal relationships/connections in the military cohort.
Mark Williams: The important point of a risk assessment is that the body of evidence must be weighed and then a professional judgement call must be made based on that confidence in the evidence. Furthermore, a study must look at the full scale of a toxicant's effects, from a level that will produce an adverse effect to a level that will not produce an adverse event, called a point of departure. In occupational and military exposures, a person is not exposed to a single toxicant, but to a variety of them and each at a different level, termed a complex exposure, which makes it difficult to know which chemical or chemicals and how much of each caused the insult. That multiple exposure dampens the confidence in the research.

Session 4: Administrative Session/Committee Discussion

The original scheduled presentation, "Department of Defense - Defense Advanced Research Projects Agency (DARPA): Biological Technologies", presented by Jean-Paul Chretien, MD, Ph.D., Commander, Medical Corps, US Navy, Program Manager Biological Technologies Office, DARPA and Thomas Thomou, Ph.D. Senior Scientist & Engineer, DARPA, was cancelled by the presenters and will be rescheduled for a future meeting.

Dr. Walker initiated an administrative session. It would be open to the public, but the committee would not be taking any public questions or comments.
Bottom Line Up Front (BLUF): The committee decided to form several new subcommittees to research and develop new recommendations. The committee decided to add another parent meeting during the summer of 2023. The tentative date for that meeting was June.
An abridged accounting of the discussion follows:

Ron Brown: Many research studies, such as those conducted by Congressionally Directed Medical Research Program (CDMRP), are not used. In the various volumes of GWI research, there were an estimated 180 or more research papers, but only 76 studies were used for all 10 volumes. No new research was used. Why can't the other studies, even if they are pilot studies, be used? [Mr. Brown is referring to *Gulf War and Health* published by NASEM.]

Tom Mathers: Could the question be clarified?
Drew Helmer: In a VA/DOD sponsored GWI State of the Science [2020] meeting many smaller studies (i.e., pilot, proof of concept), were presented. Following that meeting the RAC reviewed and put together a comprehensive summary of those projects. Ron's point was that how can we as a committee utilize or promote all those promising research projects and accelerate them into larger basic research or clinical studies.
Ron Brown: Agrees with Dr. Helmer about promoting new research. Referring to *Gulf War and Health*, he again rhetorically asks how can new conclusions or results be made if you only use the same data sets over and over?
Ken Ramos: Those are valid points, but a NASEM report may not be the correct vehicle to access that data, act on that data and then to propose studies. The NAM (National Academy of Medicine) can only use peer-reviewed and published data. It cannot use case reports or word of mouth.
Ron Brown: Can the VA write a contract to incorporate appropriately vetted studies into those reports?
Ken Ramos: The NASEM can look at that information but cannot make conclusions or recommendations based on that information. The work around would be for the VA to create its own group.
Dr. Woody: Using anecdotal data or uncontrolled experiments/trials is often misleading. It is more cost and time effective to conduct and use proper research studies.
Jim Baraniuk: Is everything published reviewed for the committee reports?
Cheryl Walker: Yes. For committee reports all evidence is reviewed. Furthermore, no peer-reviewed published data is forgotten or ignored. It is available and used by other researchers when planning experiments. The NAM has a prescribed way of looking at data and no matter how good and how much information is presented, the NAM follows its guideline. Perhaps a new approach should be considered by an alternative group.
Elaine Symanski: The NAM guidelines are not to exclude smaller studies, but to be careful when considering them because a project with a small research population may have one conclusion, but that same experiment repeated with a large study population may derive a different result.
Ron Brown: It is frustrating that there are only 76 articles used in all ten volumes of Gulf War and Health. The other research that was relevant but excluded represent millions of dollars of wasted money. There also needs to be an increase in the follow-up with GWV after the study.
Elaine Symanski: Agrees that the research evaluations should be incremental and increased based on new reports and new ways of addressing different problems. Those smaller research projects need to be combined into larger studies with increased subject numbers.
Sonya Smith: There is frustration with GWV about the research. There needs to be better follow-up and a clear representation of the research so GWV can understand and make sense of it. Also, what is the state of the Gulf War/Desert Storm Registry?
Karen Block: HOME manages the Desert Storm registry and others, and those registries are still active. However, research does not have access to those registries.
Drew Helmer: Because of the PACT Act how the registries work and share information is going to change.
Peter Rumm: HOME Director of Policy offered to address the committee by phone. Although not overseeing the registries, he does work with the doctors who do. They are also opening a telemedicine group called At HOME. Every GWV is eligible for the Airborne Hazards Registry. There are also further updates with the registries, and he recommended that the committee invite one of the doctors he works with to speak to committee and give an update.
Cheryl Walker: A registry update would be great for the next meeting.
Sonya Smith: Will there be feedback from the February 7 Veterans Engagement Session (VES)?
Karen Block: Yes, the standard operating procedure (SOP) is the minutes from the VES will be

written and sent out to the committee. Also, a VES update is presented at the subsequent parent committee meeting.
Cheryl Walker: Great. We can review those minutes before the next committee meeting in September. Also, it is suggested to add another parent committee meeting between this time and September. That would allow the committee, as a group, to think about the new recommendations to the VA Secretary.
Tom Mathers: I would like the chance to dig-in and review the previous recommendations which would allow for an informed opinion on future advice recommendations.
Cheryl Walker: Two points in response to Tom's input. First, Marsha Turner will resend all the previous recommendations for all committee members to review. The committee will review previous recommendations and be prepared to discuss and prepare new RACGWVI recommendations to the VA Secretary along with recommendations/changes for the 2024 budget. Second, to start the process the committee should consider a list of important GWV issues and prioritize them. Once prioritized the parent committee can then form subcommittees to deep-dive and work on those issues. To ensure there is time to fully develop the new recommendations the committee should consider adding an additional meeting in or around June.
Ron Brown: The new subcommittees need to have a balance of Veterans and researchers.
Cheryl Walker: Subcommittees can be self-selected. Each subcommittee's task will be to develop and research new recommendations and present them to the full committee. There can only be two or three final formal RACGWVI recommendations.
Tom Mathers: Questions the efficacy of the 2021 set of recommendations, how are those programs initiated and information provided to GWV?
Drew Helmer: There is a formal procedure to writing up the recommendations.
Tom Mathers: Questions how to measure the effectiveness of the recommendations. If money is being allocated to the process how does anyone determine the return on investment.
Ken Ramos: Due to transition in committee leadership and members, some information and initiatives were tabled. Going forward, those previous recommendations can be not only revisited but the current committee can start to investigate how to measure their effectiveness. That process can also be applied to all new recommendations.
Tom Mathers: The point of the committee is to take all the information and help advise the chairs on how to apply it and to stay within the mandate of the committee purview.
Cheryl Walker: The goal of the RACGWVI is to make recommendations to the VA Secretary concerning the Gulf War research program. However, if a committee member(s) feels there are important previous ideas or recommendations that should be reviewed, then we will address them.
Ken Ramos: Asks Tom to clarify his previous comment.
Tom Mathers: Using the Gulf War Registry as an example, how do we get more Veterans engaged in the registry. The tools all seem to be out there, but the response is limited. There also seems to be a lack of discussion on that topic placed on the agenda.
Cheryl Walker: Agendas are discussed and set ahead of time. Future agendas are open, and any topic suggestions are welcome. We can include a registry update for the next meeting.
Tom Mathers: Asks how to develop a study that involves CFS, COVID-19/Long COVID and GWI because those diseases share several common elements? Stating there is a lot of information available, and how does/can that information be turned from publication results and into actional items in a clinical setting.
James Baraniuk: Asked the committee how to allow non-VA researchers the ability to advertise their studies within VA facilities, i.e., put a poster on the wall.
Drew Helmer: Each recruitment decision is made by each individual VA facility and their IRB.
James Baraniuk: That is a confusing process and seems to have no consistent policy or oversight.
Karen Block: Molly Klote, Director, Research Protections, Policy & Education Deputy Chief

Research and Development Officer will address the committee tomorrow (Feb. 9). She is the expert and should be able to address questions concerning recruitment policies.
Dr. Woody: Could the VA send an email to all Veterans about any research study, clinical or non-clinical being conducted by the VA? There is no centralized resource for study information.
Tom Mathers: Only if the Veterans opt in to participate in studies can they be contacted. Contacting Veterans to participate in studies seems to be a systemic problem. The committee could put forth a recommendation for that problem to be addressed.
Ron Brown: If research projects could advertise in several Veteran specific magazines, they could reach thousands of GWV.
James Woody: Based on previous notification letters sent to GWV from the VA there is a mechanism in place. Can that mechanism be adjusted and utilized for clinical study notifications.
Bill Watts: Due to the complexity of the VA clinical studies website GWV will not use it. They prefer trusted social media websites and nonprofit groups. (Bill) also emphasized the trial description cannot contain scientific/medical jargon. It must be written at a ninth to tenth grade reading level.
Tom Mathers: Will VA allow non-vetted clinical research study information to be advertised?
Ron Brown: The studies are approved and funded. What's the problem?
Bill Watts: The greatest hinderance to recruitment is that for a large square foot, multistory hospital there is only one, eight by ten piece of paper with the study information.
Tom Mathers: The question becomes how do we consent every GWV who comes into the VA to be contacted for participation in a study?
Drew Helmer: The VA is developing a research information hub, the RAC heard a presentation on it [David Thompson, VHA ORD Research Volunteer Registry, Sept. 2022]. The problem remains that not all Veterans trust the VA and not all Veterans want to be contacted about research studies. Contacting Veterans regarding research studies is a facilities decision. That decision also affects recruitment in a VA facility. The study can be Federally funded, and IRB vetted, but the decision remains with the individual VA facility.
Cheryl Walker: The overall problem is lack of intra-, and interagency cooperation and data sharing. Currently the NIH is addressing that problem, and this might be a good time for the RACGWVI to address and recommend similar changes.
Tom Mathers: Leadership is the problem regarding this issue.
Cheryl Walker: Recommends two subcommittees; first, research issues associated with accessing VA resources from human resources to biological specimens. Second, engage with Veterans about participation in research studies. She addressed a comment made in the VES about establishing specialty clinics for Veteran groups.
Drew Helmer: Those are called post-deployment clinics or registry clinics. Those clinics could conduct research based on past and present experience and develop a model of care. A model was presented by Lisa Mc Andrew at the September meeting.
Cheryl Walker: Suggests establishing GWI integrated clinical model at regional VA healthcare centers.
Ron Brown: The problem is VA is reactive care, not proactive.
Bill Watts: The VA doctors need specialized training to treat GWI/military toxic exposures. Suggested developing a GWI educational team to travel to VA centers and present information to the staff and GWV.
Jane Wasvick: Supports the idea of regional specialized clinics.
Ron Brown: Supports the development of the clinics.

Cheryl Walker: Recap of the discussion.

- How do we scale intergenerational studies?
- How do we provide integrated care to Veterans whether that be specialized clinics for their cohorts, integration of Individual Longitudinal Exposure Record (ILER), and/or provider education on those topics?
- The development of an alternative vehicle for utilizing data other than the Institute of Medicine (IOM).
- How to increase research information in VA facilities and in the GWV community.
- Ways to increase access and sharing of research materials and repositories.

Sonya Smith: How can we leverage the Veteran Experience Office (VEO)? Their job is to build trust in the Veteran community.
Cheryl Walker: Closed the administrative session returning to the scheduled agenda presentation.

Session 5: Individual Longitudinal Exposure Record (ILER) Update and Wearable Capabilities to Assess Military Exposures

— Steven Jones, MPH, Director, Force Readiness and Health Assurance Policy, Office of the Deputy Assistant Secretary of Defense for Health Readiness Policy & Oversight

Dr. Jones informed the group that Larry Vandergrift is part of the meeting and would present a demonstration on the wearables and the ILER.
Dr. Jones introduced himself with brief description of his background and work which includes being a GWV.
The purpose of the exposure monitoring program is to help mitigate toxic exposures as well as record the amount and type of toxic exposure to assist with medical diagnosis and treatment. Military toxic exposures can happen in garrison, during training and when deployed. They can be direct, such as overhead chemical spray or burn pits fumes or indirect, such as washing a vehicle covered in soot from an oil will fire. Further toxic exposures happen at home. All of those are called total exposure health. Inhalation and respiratory exposures are currently the focus for many studies. To determine a health outcome several factors must be identified. Those are the source/type, the environmental concentration, external exposure, internal exposure and target site exposure. The more data collected about each of those factors helps to improve the health outcome, which is why exposure monitoring via individual wearable devices and area environmental monitoring are essential. Current DOD/HRPO (Health Readiness Policy & Oversight) areas of focus are exposure monitoring, which is focused on reconstructing past exposure, assessing current exposure and predicting future exposures, toxic exposures which uses a phased approach to gather toxicity information for new substances and Individual Longitudinal Exposure Records (ILER).
Dr. Jones transitioned to the comprehensive exposure monitoring (CEM) and capabilities-based assessment (CBA). Those represent a full look at exposures. What and where are the gaps in measuring exposures? How to fill the identified gaps? The CEM/CBA process is a continuous cycle: Plan, Prepare, Collect, Integrate, Analyze, Disseminate, Assess. Dr. Jones summarized the wearables program objectives which is to determine how to safely and securely outfit troops with the monitoring devices in ways that will not impede their mission and then retrieve and analyze the collected data.
Dr. Jones transitioned to the ILER overview. ILER is a web application that compiles, collates, and presents available occupational and environmental exposure information in an individual/person-centric format. It will create a longitudinal (historic) exposure record for medical care and research and toxic exposure situations. The ILER V1.0 program was initiated in 2019, now at v2.2.

Committee Questions and Discussion:
Bill Watts: Will the monitoring include support personnel, such as mechanics who did not receive frontline exposures?
Steven Jones: Yes.
Tom Mathers: How is data captured in the ILER and is it organization specific, (i.e., VA only)?
Larry Vandergrift: ILER does not include private care/insurance. ILER is filled by several sources including the DOD. VA contributes Gulf War and Burn Pit registry information only. There is also some self-reporting.
Tom Mathers: How do you capture the largest cohort of GWV into the ILER?
Larry Vandergrift: From registry data and medical records.
Steve Jones: Emphasized that the PACT Act and the National Defense Authorization Act (NDAA) requires that the ILER records and summaries be accessible to Veterans, not just doctors or professional staff. That will allow for self-reporting.
Ron Brown: Will ILER include GWV personal exposures?
Steve Jones: Due to the length of time that has passed and how the monitoring and recording of exposures was conducted at that time, there is no accurate way to include that information.
Larry Vandergrift: Steve is correct. Best data collection started in the mid-2000s.
Cheryl Walker: How can ILER data be used to mitigate health effects in GWV?
Steve Jones: Retrospectively, ILER can generate cohorts containing specific exposure information and those affected. Prospectively, researchers would be able to use the retrospective data to develop future studies as well as help to establish increased environmental safety and awareness in future deployment areas.
Cheryl Walker: Would that type of research be outside the ILER mandate?
Steve Jones: No. The researcher can request ILER data.
Cheryl Walker: Is ILER working with DARPA on exposures?
Steve Jones/Larry Vandergrift: No.
Cheryl Walker: DARPA was scheduled but unable to present on their exposure project. Are the ILER and DARPA projects related or similar?
Larry Vandergrift: There was one conversation around 2017. No further contact/discussion.
Tom Mathers: Despite the limitations, is there value in building a GWV exposure cohort?
Steve Jones: It could be done, but there will be significant limitation on collecting good data.
James Woody: How will Veterans be told about ILER and how to use it?
Steve Jones: That will be up to the VA on how to do ILER outreach and education.
Ron Brown: Several GW cohorts were tracked. Will that information be added to ILER?
Steve Jones: Individual information is difficult to find, verify and apply to the ILER algorithm.
Ron Brown: Can a person's unit information be used?
Larry Vandergrift**:** Yes, some of that information has been added.

Part 2 of ILER Presentation.

Larry Vandergrift presented the function and capabilities of the ILER. Any personal information shown was deidentified/redacted. Mr. Vandergrift highlighted several functions of the ILER he felt would be of most interest to the committee as those would be the functions used by clinicians, researchers or claims adjudicators. ILER categorizes medical conditions associated with different exposures. Currently there are about 25 million individual deployment records from 2001 to present. From those, 10.5 million unique individuals have been mapped. The first ILER capability discussed is its ability to search by individual. That function provides clinicians, preventative medicine providers and VA claims adjudicators a person-centric view. ILER can pull an individual's exposure information based on deployment geographical location and time spent in that area, along with any registry information and health assessments. ILER also adjusts for the individual's proximity to a toxic exposure site. Documents, pictures and reports are part of the ILER. Also, older materials can be scanned in and searched for in the ILER system, which would be how many 1990-91 Gulf War records would be put into the system. Mr. Vandergrift showed an example of an exposure record, but due to the information being sanitized there were many blank areas.

Committee Questions and Discussion:

Ron Brown: How would a Veteran access the ILER website?

Larry Vandergrift: Currently there is no process. However, a process is being developed per the PACT Act, National Defense Authorization Act (NDAA) and legislative agreements.

Steve Jones: The Veteran access process is being developed by the VA and DOD. Specifically, they need to ensure there is proper patient information security.

Drew Helmer: Can you share the cohort production capability?

Larry Vandergrift: It's live now. You are looking at it. The VA and DOD care providers will have an interoperability between ILER and electronic medical records (EMR). A clinician version of the ILER will provide a record as a 78-page (length varies) PDF when printed. Because the ILER contains extensive amounts of information, some of which will not be applicable to some users, an educational course is being developed to help guide users. Mr. Vandergrift demonstrated the cohort module to show what is available in ILER.

Session 6: Committee Discussion

— RACGWVI Committee

Cheryl Walker: How would the committee feel about putting together subcommittees for developing metrics to measure the success of RACGWVI recommendations as well as developing suggestions for new recommendations?

Committee: All committee members supported the action.

Sonya Smith: Asks about working with or leveraging VEO to engage with GWV. Are there other opportunities the VA offers that the RACGWVI can use to engage with GWV?

Barbara Ward: Has previously worked with VEO on Veteran outreach. They are a good information, logistics and project execution resource.

Richard Gaard: Does every VA have a VEO?

Drew Helmer: Yes. Agrees the VEO is a good resource, and they already have several outreach programs the RACGWVI could work with. John Boerstler is the VEO Chief.

Ron Brown: The VA previously sent out newsletters containing GWI specific research updates and studies. Can that be restarted even as an electronic/digital format?

Cheryl Walker: That suggestion should be added to the Veteran Outreach subcommittee.

Delphine Metcalf-Foster: Encouraged committee members to work with outreach groups and committees at their local VA facilities to help effect local policy changes.

Ken Ramos: Regarding Dr. Block's presentation, was the memo a onetime or a standing

memorandum of understanding (MOU) for collaborative studies?
Karen Block: The MOU was a onetime only.
Ken Ramos: A blanket MOU for interagency agreements between universities and federal government facilities concerning research projects would be beneficial. Second question, are the biorepositories you mentioned open for general research use?
Karen Block: Yes, but there are many official steps, discussions, and paperwork involved in the process. Currently we are trying to have all those researchers make their data public.
Ken Ramos: Do you know how that information has been disseminated for investigators outside the VA to access as a resource?
Karen Block: The information isn't widespread but is confident the GWI research community knows about it. Regarding the biorepositories, their resources are limited in both quantity and tissue type.
Elaine Symanski: What biorepository are you referencing?
Karen Block: CSP 585.
Elaine Symanski: How does a researcher find out what is available at the repository?
Karen Block: The CSP 585 website.
Ken Ramos: Both the lack of awareness and the difficulty of navigating each VA's access request process, especially if a researcher doesn't have a contact at that VA, is emblematic of the problems that slow or prevent GWI research.
Cheryl Walker: Asked Dr. Block provide a brief overview of the cooperative studies program and how someone accesses the program.
Karen Block: ORD's Cooperative Studies Program is geared towards NAM research projects that work with large cohorts, have several subject matter experts and use state-of-the-art technology.
Cheryl Walker: They are not outside researchers. They are doing this research with the VA, correct? How does an outside researcher access those samples?
Karen Block: An investigator must partner with the VA through an IPA.
Ken Ramos: The committee should recommend or develop a mechanism that allows for non-VA investigators to partner and/or collaborate with VA-based investigators.
Cheryl Walker: The NIH established such a collaborative process.
Karen Block: The VA and DOD don't have the resources like NIH.
Cheryl Walker: Collaboration isn't about scale but more about the value of partnerships.
Ken Ramos: There is interaction between the VA and military, but it ends there. Many new investigators proposing and getting funding for research projects don't know about, or how to access samples. More than 80% of applications have nothing to do with military.
Ron Brown: Said he knew a Dr. Chao was able to access the DOD sample repository and information on specific Veteran cohorts when other researchers could not. He feels there should be a standardized process made available for all researchers.
Drew Helmer: As a VA-based researcher it can be difficult to find DOD collaborators. The committee could investigate a process, specifically in terms of GWV, to identify what resources are available, such as data, specimens and SME and advertise and promote that knowledge to facilitate GWV/GWI research.
Cheryl Walker: Agrees with Drew Helmer.
Elaine Symanski: The sample repositories need to be dynamic and routinely updated.
Ron Brown: Are sample repositories separated into categories such as eras, service area? Drew Helmer: Yes, each repository does separate samples, however, they all may do it differently. Karen Block: In Durham, North Carolina 207 funded research studies were reviewed. When the funding managers were asked to show every study that had human subjects or might have data or specimens available from which an inventory data base could be established, fewer than 20 provided the information. A new policy is being pushed to make sample inventory sharing mandatory. This could be a future presentation if the committee is interested.

Tom Mathers: The goal is to have investigators return samples to the biorepository.
Karen Block: Yes. That process allows for study validation or for use in another cohort.
James Baraniuk: The Boston Biorepository, Recruitment & Integrated Network for GWI (BBrain) repository already does that.
Cheryl Walker: Where is the metadata stored?
James Baraniuk: It is a part of the repository, on their website.
Karen Block: Those samples are deidentified. Samples cannot be traced back to medical records. That is a study limitation.
Tom Mathers: Do VA records link to non-VA records through the EMR database?
Karen Block: That depends on the consent form.
Tom Mathers: Is there a way to remind people, both inside and outside the VA, about the database and increase participation?
Drew Helmer: The Million Veteran Program (MVP) is a model platform for doing that. There are approximately 135,000 GWV participants.
Tom Mathers: How many of them are diagnosed with GWI?
Drew Helmer: Of the approximately 41,000 GWV who completed the GW survey, approximately 14,000 or 30 percent were diagnosed with GWI.
Ron Brown: Is that the same number the VA has been tracking?
Drew Helmer: No, that was an epidemiologic study created in 1995. Current studies are limited because original patient consent did not include provisions for long-term storage and/or other investigators using those samples.
Ken Ramos: Drew, are you working from the Phoenix repository.
Drew Helmer: Tucson
Drew Helmer/Ken Ramos/Karen Block: All discussing the locations of sample repositories. VA project IN-DEPTH is working with the Tucson repository. Some of the repositories contain COVID samples along with others. MVP is based in Phoenix. A presentation on the repositories could be interesting and educational.
Cheryl Walker: Asks for comments from online committee members. Based on the conversation, subcommittee 1A will be Human Resources Engaging of GWV in research; 1B would research how to access the various biorepositories for research.
Drew Walker: Can we invite a guest to talk about how to access the DOD repository.
Karen Block: That would be Dr. Kelley Brix.
James Baraniuk: The CDMRP cut GWI specific funding by converting GWI research into a blanket term Toxic Exposure research. Can the committee recommend that GWI specific research funding go back to previous amounts?
Karen Block: That is a Congressional decision.
James Baraniuk: Has toxic exposure research become the all-encompassing term for all military toxic exposure in the Southwest Asia theater from the 1990-91 Gulf War to current? If so, will a new Toxic Exposure RAC be formed?
Karen Block: Do not confuse CDMRP and VA. The purview of this committee is to oversee the health consequences of the 1990-91 GWV in the Southwest Asia area of operation.
Cheryl Walker: There was not mention of toxic exposure in the 2021 recommendations.
Tom Mathers: Was the toxic exposure program absorbed by the Gulf War-Military Exposure Research Innovation Center (GW-MERIC)?
Karen Block: The GW-MERIC is separate from the RACGWVI in both purview and budget.
Cheryl Walker: The GW-MERIC recommendations were worded for the 1990-91 GW.
Ron Brown: I would like the committee investigate GWV suffering from sleep apnea.
Cheryl Walker: Please explain.
Ron Brown: There are multiple peer-reviewed, published research articles showing GWV suffer from a higher incidence of sleep apnea than control groups. The committee could recommend the

VA Secretary investigate that further.
Tom Mathers: To study sleep apnea in the Gulf War cohort?
Ron Brown: Yes. VHA studies show, when compared with Vietnam, OIE, OIF the GWV have a higher incident.
Tom Mathers: Your question is why and then what can we do about it?
Ron Brown: Yes.
Cheryl Walker: We could discuss adding sleep apnea to section one of the 2021 SECVA recommendations.
Tom Mathers: What projects listed under section one of the 2021 recommendations have been conducted or started? Also, would the committee be open to new research suggestions for 2023 SECVA recommendations?
Cheryl Walker: For our next meeting we can do a portfolio review to assess the recommendations.
Tom Mathers: Regarding the biorepository, researchers need to have access so they know what kind of questions they can ask and research they can conduct.
Cheryl Walker: I concur. One of the 2021 recommendations is to determine the utility of the DOD serum repository as a resource for investigators. We are still talking about it today.
Karen Block: We can look at that and other suggestions. They were all developed in a State of the Science meeting under Dr. Steinman. I can discuss them at another meeting.
Cheryl Walker: A full recommendation portfolio review would be appropriate at the next meeting, to ensure there is correct focus and funding on the recommended projects.
Tom Mathers: Are any of those areas currently unfunded?
Karen Block: Microbiome is heavily funded. Latent GWI-related issues such as dementia, accelerated aging, and intergenerational effects.
Cheryl Walker: The committee may even develop a new one.
Ken Ramos: Is there a window of time between approving the recommendation, acting on and completing them?
Karen Block: Based on the level of activity, a topic can be re-examined.
Ken Ramos: For our next recommendations the committee should consider including a project timeline to ensure productivity.
Cheryl Walker: That concludes the committee discussion time. We now open the meeting to public comments.

Session 7: Public Comments
— Visitors and Invited Guests
Bill Watts: Has several questions submitted via the live chat. He also reminds everyone to please remain polite when speaking.
Chat: Does the study mentioned by Dr. Baraniuk require travel to Boston?
James Baraniuk: The BBRAIN study and active enrollment is closed, however, interested people can still be added to the information repository for future studies.
Chat: Why doesn't the committee advertise meeting and study information on T.V. and other large media outlets?
Cheryl Walker: The cost.
Karen Block: Pertaining to studies, advertising would fall under the study guidelines and the IRB. Also, the cost.
Chat: Why do all the VA differ in their level and type of care? Also, the research is done differently. There is no consistency.
Drew Helmer: That is not in the committee purview. However, as a VA employee and doctor, each VA does its best to work with and cater to the variety of people and eras of Veterans in the areas the facility has established.

Chat: Has anyone studied the effectiveness of equine therapy?
Tom Mathers/Cheryl Walker/Karen Block/Sonya Smith: Yes, regarding Post-Traumatic Stress Disorder (PTSD), depression and other similar mental health issues, it is very effective. Unknown if it was applied to GWI specifically.
Female GWV: Asked about another GWV who was supposed to ask a question/make a comment to the committee.
Female GWV: (*in summary*) The Veteran commented extensively about VA and DOD institutional betrayal, RACGWVI dysfunction, which includes irrelevant speakers and presentations, not following the agenda and off-base meeting location. She also vehemently demanded for a GWI ICD code and mandatory healthcare provider GWI education.
Bill Watts: Thank you for your comments.
Male GWV: Thanked the committee. Speaker is a former committee member and states many of the complaints made in this and previous meetings were the same from when he served years ago. Addressing sleep apnea (which is a Veteran-wide issue), the committee previously suggested such a study, but it failed due to lack of GWV follow-on participation, which has remained a chokepoint for multiple clinical studies. He recommends moving past pilot studies and moving into large participant trials.
Bill Watts: Thanked the GWV for his comments and asked that he send his further comments to the RACGWVI email.
Male GWV: Says that CPAP (continuous positive airway pressure) machines collect data, the VA should have that data and it can be applied to a sleep apnea study. Commended the ILER presentation and the two speakers. He feels that any ILER information gathered on GWV could have problems because records regarding vaccines, troop locations, deployment and other similar information was not accurately recorded.
Bill Watts: Thank you.
Female GWV: (*in summary*) The VA needs to establish a RAC to address GWV claims and clinical care. The follow-on clinical studies failed due to lack of funding. The CDMRP military toxic exposure program appropriated the GWI study money. Recommends that the VA needs to establish a GWI-specific clinic at each major VA healthcare facility. Establish an ICD code for GWI. As GWI research is published, the RACGWVI should email that information to every VA healthcare provider to save them the time of looking.
Bill Watts: Thanked the speaker for her comments; specifically, for pointing out the RACGWVI is a research committee. It does not deal with Veteran claims or compensation.

Closing Remarks:
Cheryl Walker: Officially closed the meeting. She thanked all the Veterans and speakers who participated.
Meeting Adjourned.

Day 2: February 9, 2023

Session 1: Welcome / Opening Remarks

— Kenneth Ramos, MD, PhD

Thanked everyone for joining the meeting and for making day one so successful. He asked the committee members to introduce themselves.

Session 2: Million Veteran Program (MVP) Overview

— Sumitra Muralidhar, Ph.D., Director, Million Veteran Program VA Office of Research and Development

Dr. Muralidhar provided the committee with an update to the Million Veteran Program (MVP). The MVP was established as a database of genetics, health, military experience and exposures. The amount of one million was chosen because the program covers Veterans of all eras, and it would give the best statistical values for each Veteran cohort and for study data sets. The goal of MVP is to help establish how genetic, lifestyle, military experience and exposures interact to inform on health and aid in the development of individual/personalized medicine. To join MVP a Veteran completes the consent process, provides a tube of blood and completes a survey. The process can be initiated online from home. Currently MVP has 930,000 Veterans enrolled and is the world's largest genomic database and curated genotype linked to a healthcare system. All sensitive/private patient information (e.g., social security number, full date of birth, home address) is redacted from their sample and the sample is given a barcode. The samples and information are shared with collaborators in the VA (VA Informatics and Computing Infrastructure (VINCI) & Military Health System (MHS) Genesis), Dept. of Energy (DOE) (Oak Ridge National Lab) and VA Data Commons (U of Chicago).

Demographics: 91% Male/9% Female; 70.99% White; 17.3% Black (147K+); 8.2% (~70K) Hispanic; 2.88% multi-racial; 1.07% Asian; 0.75% Native American/First Nation; Average age 67 years. MVP includes over 75 research projects; works with 600+ investigators; over 35 VA and DOE research sites; noted in over 200 publications.

Research Priorities: Hannon Act is precision brain and mental health initiative. Cancer Moonshot 2.0 is an initiative to reduce cancer death rates by 50% over 25 years. PACT Act/Military Exposures will have access to the MVP database. MVP-MIND (Measures Investigating Neuropsychiatric Disorders) will examine how lifestyle, genes and military experiences affect mental health and to help identify new biomarkers and treatments.

MVP Surveys: Baseline (health, health history, family history) 558,000 participants; Lifestyle (nutrition, exercise, smoking, substance use, military exposure, mental health) 437,000 participants; Gulf War 44,000 participants; COVID-19 255,000 participants.

Future Initiatives: Reach one million participants. Increase diversity of enrollees. Expand data access to researchers in and outside VA. Increase breadth and scope of scientific projects. Move scientific discoveries into the clinic. MVP is starting a taskforce to explore a process to integrate MVP with ILER and the military exposures program.

Committee Questions and Discussion:

Cheryl Walker: Do you see a possibility for MVP working with the DOD serum repository in terms of pre-deployment health data?

Sumitra Muralidhar: MVP is working on that, but it is difficult to gain access to the DOD repository. Any help the committee could provide would be appreciated.

Cheryl Walker: Access to the DOD repository is being discussed by the committee and we will stay in contact with you regarding that topic.

Drew Helmer: What is the timeline for non-VA researchers to access MVP through the U of Chicago Data Commons?

Sumitra Muralidhar: Hopefully pilot studies will begin in 2024 and based on results/feedback fully open by the end of that year.
Drew Helmer: Will access require funding or a specific mechanism?
Sumitra Muralidhar: Those processes are being developed.
Tom Mathers: Encourages MVP to expedite the access process, to not make it contingent on federal funding but to include corporate sponsors. Also, the faster full access is granted to all researchers the faster information can be learned and treatments can be developed.
Sumitra Muralidhar: That is the final goal of MVP and to get there as fast and safely as possible. Also, all the summary statistics of all MVP studies are deposited in the NIH dbGaP (database of Genotypes and Phenotypes) portal.
Sonya Smith: How does MVP conduct Veteran outreach, especially for African American Veterans?
Sumitra Muralidhar: MVP partners with the Office of Minority Veterans and attends several Veterans Care Agreements (VCA) conventions. MVP is also developing a focused recruitment plan with the Veterans Experience Office to help increase diversity and outreach for the program.
Elaine Symanski: Two questions: How representative of the sample population is relative to the source population regarding ethnic diversity and conflicts served in? What is the follow-up process by MVP, does it follow Veterans or link to an EMR?
Sumitra Muralidhar: MVP is aligned with the source population. It is open to all Veterans, not just Veterans receiving care through the VA. However, the program routinely reexamines demographic statistics to ensure good statistical diversity and enrolment.
Dr. Curtis Lowery, VA Associate Chief of Staff (ACOS) Pacific Island Region (audience participant). The Pacific Island Region, due to being remote and spread out, is an underserved region. Is there an incentive program to help engage and recruit from those populations across the island region?
Sumitra Muralidhar: There is an MVP site in Honolulu and MVP does have some outreach programs that we can discuss.
Jim Baraniuk: How is the data being used to advance GWI?
Sumitra Muralidhar: There is one major GWI-related MVP project.
Ken Ramos: Please respond to Elaine Symanski' s question regarding participant follow-up?
Sumitra Muralidhar: MVP does have permission to recontact participants. It also sends out an annual newsletter. Currently the program is developing ways to reengage the cohorts and understand what they would like to see come out of MVP.

Session 3: VA Research Processes and Protections

— Molly Klote, M.D., CIP, Director, Research Protections, Policy & Education, Deputy Chief Research and Development Officer -Enterprise Support, VA Office of Research and Development (ORD).

Dr. Klote introduced herself and proceeded to give the committee an overview of ORD's three-fold mission. 1: To improve Veterans health and well-being via basic, translational, clinical, health services and rehabilitation research. 2: To attract, train and retain the highest-caliber investigators and nurture their development as leaders in the field. 3: To assure a culture of professionalism, collaboration, accountability and the highest regard for research volunteers' safety and privacy. ORD has five strategic priorities: Increase Veteran's access to high-quality clinical trials; increase substantial real-world impact of VA research; put VA data to work for Veterans; actively promote diversity, equity, and inclusion within our sphere of influence; build community through VA research. Funding for VA research comes from VA research appropriations, other Federal agencies, industry and nonprofit groups which amounts to approximately two billion dollars of VA research funding. All research funding follows a specific review process, and only VA-based or VA-affiliated researcher(s) can receive VA research money. The VA funds approximately 550 new

research projects each year. The VA has a partnered research program to allow for non-VA industry sponsored clinical trials. All outside sponsored clinical trials are vetted by the VA to ensure study safety and protection for participating Veterans. The VA Innovation and Research Review System (VAIRRS) is the VA's enterprise instance of IRBNet. VAIRRS will be used by all VA medical centers with research programs and will provide an enterprise platform to support the management of research oversight committees. The transition to this new online submission and review system began in October 2020. Currently, VAIRRS supports 106 VA research sites. VAIRRS maintains a database that maintains all research projects and their locations. There are approximately 19,000 VA-based projects being conducted across the country, such as MVP which is being conducted at 65 different facilities. The program also allows searches based on keywords. For example, a search using "Gulf" returns 177 projects with 44 different sponsors at 38 different VA sites with 101 principal investigators conducting GWI research. The goal of the project is to move from multiple VA medical centers independently conducting research to a unified and integrated enterprise system. Dr. Klote discussed several categories of research from minimal risk and regulation to high risk and maximum regulation and oversite (e.g., quality improvement, clinical human trials, respectively). VAIRRS is working to integrate the research infrastructure to include Electronic Health Record (EHR), the volunteer research program, clinical trial management and research billing.
To see all GWI ORD funded clinical trials go to VA Gulf War Research Program (research.va.gov). For projects outside VA use ClinicalTrials.gov search term Gulf War Syndrome. VA Research Volunteer Program was initiated during the COVID pandemic and received 57,000 participants in 75 days. After the pandemic, it has become a VA-wide, centrally managed program to link research volunteers to VA research resources and research opportunities. The continuing goal of the program is to create a sustainable and modernized connection between VA researchers and volunteers. Other ways researchers can access VA data are through informed consent for future use and surveys completed which are implied consent, or through HIPAA (Health Insurance Portability and Accountability Act) authorization/waiver which must have IRB approval. The VA cannot sell patient information.

Committee Questions and Discussion:
Cheryl Walker: Is there a move to have controlled interagency broad access MOU for sharing consented samples.
Mary Klote: Yes, there is currently one with the DOD.
Tom Mathers: The VA should re-examine its policy of sharing de-identified samples with outside agencies because doing so could accelerate research without compromising patient information. The VA should re-examine its policy regarding competing clinical trials (VA vs. public) accessing VA samples because, again, that only serves to accelerate the research process. Who currently adjudicates that process?
Mary Klote: There is a board that oversees the outside research, and they honestly evaluate the merit of allowing non-VA researchers access to VA samples even if there would be study competition. Furthermore, the VA does not own the Veterans. They are free to participate in any study they want.
Jim Baraniuk: As a non-VA researcher, is there a standardized protocol to allow for recruitment within a VA?
Mary Klote: There is no standard protocol regarding recruitment in the VA. Advertising in a VA is decided by that VA medical center director. Part of that decision is, by allowing recruitment at the VA, it signals the VA endorses that outside research project, and then what happens if a Veteran is injured in that study? How will it reflect on the VA? Those questions must be considered.

Session 4: Veteran Perspective: 1990-91 Military Exposures

— Mr. Ronald Brown 1990-91 Gulf War Veteran

Mr. Brown presented a GWV-centric overview of toxic exposures in the GW. His presentation included battlefield pictures taken by, and direct quotes from GWV. The images showed stark contrast between white sand and black soot from the oil well fires. The majority of the Veteran quotes spoke of developing severe respiratory issues. His goal for the presentation was to ensure the committee and all others attending understood the different toxic airborne hazards faced by GWV.

Session 5: Veteran Perspective: Gulf War Research Historical Perspective

— Mr. Kirt Love, 1990-91 Gulf War Veteran

Mr. Love presented an abridged overview of the history of the RACGWVI from its inception in 1998 as an omnibus bill to the current day 2023. He noted the first committee was allowed to self-govern and it openly challenged the VA and DOD dogma. Up to 2005 the RAC worked to actively initiate research on GWI causes and treatments that included talking to European counterparts. The RAC shifted its membership and resources to the CDMRP to reduce internal restrictions. Mr. Love provided a condensed synopsis of the Millennium Cohort, WRIISC, the Burn Pit Registry, the PACT Act and other VA programs. Mr. Love suggests there are two main research areas of concern that can lead to answers for GWI, total genomic function or alteration and residual compounds stored in the body. He further emphasizes that the VA needs to have a strong proactive approach to GWI research and treatments instead of their current approach of wait and see.

Session 6: Veteran Perspectives: Military Exposures Roundtable Discussion

— Mr. Ronald Brown, Col. Richard Gaard, Mr. Kirt Love, Mr. Tom Mathers, Ms. Delphine Metcalf-Foster, Ms. Sonya Smith, Mr. Bill Watts, Dr. James Woody (Discussion Chair).

All are Veterans of Operation Desert Shield/Desert Storm.

Dr. Woody: Opened the Veteran Roundtable Discussion. He called on the participants in their order on the agenda/program.

Richard Gaard: I think it would be of benefit to the RACGWVI for members to visit local VAs and meet with the VEO and directors to learn about their mission and how those centers are working with GWV.

Tom Mathers: One of my missions in working with the committee is to facilitate and expedite GWI research and treatment development, which if it will aid the process, support moving that research and de-identified samples to the private sector. The more knowledge we have about GWI the more we serve GWV. A second point is the need to engage young researchers and bio-medical students to conduct GWI research. Finally, GWI is a multi-symptom illness. When looking for treatments each of those symptoms must be addressed and one approach could be to identify several of the worst symptoms that are ubiquitous to all GWV with GWI and start with developing treatments for those three or four symptoms.

Ron Brown: Asks the committee to form a subcommittee to research sleep apnea and GWI.

Delphine Metcalf-Foster: Asks the committee to investigate and review outreach to the African American and women Veteran populations.

Sonya Smith: Agrees with Ms. Metcalf Foster; the VA needs more outreach to the African American and women Veteran populations. Also agreeing with Mr. Mathers' statement of needing to increase GWI research communication and outreach. The committee is comprised of many innovative people, and she is confident they could develop something. She pointed out many Veterans, especially minority Veterans do not trust the VA, and the committee needs to find a way to bridge that gap. She suggested working with MVP as their team seems to have addressed that issue.

Regarding outreach, the committee talks to Veterans but how does it leverage that information?

Bill Watts: Agreed with Ms. Smith that there is a lack of outreach to female Veterans. There is also

a general lack of outreach with the Veterans at VA facilities, and they don't know about GWI research, and they don't hear about RACGWVI meetings. Reading from a Veteran comment posted in the chat, "The engagement sessions are so important. The more we stand up and speak for the other Veterans who are left behind, the more they will listen."
James Woody: As a researcher he agreed with Mr. Love's statement that human tissue collection is important in understanding the mechanisms of a disease. Dr. Woody further supported Mr. Mathers' statement regarding GWI research collaboration between VA and private sector.
James Baraniuk: Thanked Mr. Brown and Mr. Love for their presentations, both of which served to remind the committee of the Veterans whom the committee was created to help and serve.
Kirt Love**:** When going for his WRIISC exam he requested total genomic sequencing with an analytical analysis and for fatty tissue to be removed. The exam doctor told him those were not possible, and that form of testing is years away.

Committee Questions and Discussion:
Cheryl Walker: Thanked the GWV for their perspective, input and most importantly for their service. For future meetings she would like to discuss the possibility of having a GWV speak at the opening to remind the committee of why they are there.
Drew Helmer: Thanked the Veterans for sharing their thoughts and opinions. Regarding samples, Dr. Helmer would like the committee to further explore how information is being collected, the self-reported information, the medical record data, the specimens and possibly work with MVP on how such a process could be developed, or how to improve what already exists and then how to integrate that information into the clinic setting.
James Woody: Regarding tissue samples, they are critically important when researching disease growth and impact on cells, however, tissue samples do not help elucidate mechanisms and symptoms of disease and that is where basic research is essential. It is important to remember how and why both a basic and a clinical research approach exist.
Tom Mathers: Regarding physician GWI education, what is the state of process? Are the right questions being asked and are the programs working? This should be an area the RACGWVI revisits in future meetings.
Female GWV: States she helped to establish the RAC. She encourages the committee to recommend to SECVA that the VA establish GWI specialty clinics for care of GWV.
Ken Ramos: Thanked the presenters and the roundtable Veterans.

Session 7: Acute exercise tolerance among Veterans with Gulf War Illness

— Jacob Lindheimer, III, Ph.D., Deputy Associate Chief of Staff/Research, William S Middleton VAMC, Madison, WI

Dr. Lindheimer thanked the committee, introduced himself and described how he came to be a VA researcher. Specifically, he was fascinated with how some forms or levels of exercise can be harmful to some individuals. Key terms for his presentation were Post-exertional Malaise (PEM) defined as a short-term condition where symptoms are exacerbated 24-48 hours flowing physical or cognitive stress. Adverse Event (AE), an undesirable or harmful outcome that occurs during or after an intervention but is not necessarily caused by it. AE sub-terms were Serious, e.g., death from heart attack, and non-Serious, e.g., fatigue. Based on previous research, chronic multisymptom illness (CMI) has an elevated risk for non-serious AE within a few minutes and up to a week following exercise. A limitation of that study was the exercise/exertion levels were high to purposefully evoke AE events. That level of exercise is not standard for rehabilitation practice. Dr. Lindheimer's study aim was to examine dose-response relationship between exercise-intensity and 1) psychometric outcomes, 2) biological outcomes, and 3) behavioral outcomes. The hypothesis: relative to lower intensity exercise, higher intensity leads to 1) increased symptom

severity, 2) increased sensitivity to experimental pain stimuli, 3) decreased cognitive performance, 4) increased inflammatory cytokines, and 5) decreased physical activity. The study was conducted under randomized controlled crossover experiments that started with pre-test outcomes, a randomized exercise event based on heart rate reserve and post-test outcomes.
GWV participating in the study met the Kansas definition of GWI. Group demographic: 90% male, 95% white which represents the GWV population in Wisconsin, the study location. Those GWV also scored differently on the Kansas GWI questionnaire, such as on pain severity, and those scores were used in determining results data. The study measured fatigue symptoms, pain sensitivity and cognitive performance in each category based on the stress level of the exercise. Initial results showed there was little difference between low and high exercise exertion, however, exploratory findings showed significant individual differences suggesting further analysis breakdown is needed. Study conclusions suggest that on average, aerobic exercise intensities greater than 75% of maximum heart rate did not lead to greater risk of non-serious AE. Regular moderate-to-vigorous physical activity, 75% of maximum heart rate, should be encouraged as part of the overall wellness plan for Veterans with milder CMI symptoms and lower risk of serious AE. Dr. Lindheimer reviewed the limitations of the study and how to improve those for future studies.

Committee Questions and Discussion:
Cheryl Walker: What are your future studies?
Jacob Lindheimer: To focus on advancing clinical research to work for Veterans.
Cheryl Walker: Are you participating in the Partner Research Program with industry?
Jacob Lindheimer: I have not heard of that, so no, but I would be interested in learning more about it.
Chat: What Kansas definition did you mention?
Jacob Lindheimer: The definition established in 2001 based on the symptoms that define GWI.
Chat: How does a Veteran get included in the Kansas study model?
Jacob Lindheimer: The WRIISC has educational resources and personnel that can help. Also, the Kansas definition is widely available.
Ron Brown: What was the range of symptom severity among the GWV in your study?
Jacob Lindheimer: There was a wide range from severe to mild, with most of the population in the moderate range.
Tom Mathers: Will the cytokine data be presented at future meetings or published?
Jacob Lindheimer: That data is currently being processed and will be shared when completed.
Cheryl Walker: Thanked Dr. Lindheimer and moved to the next session on the agenda.

Session 8: Committee Discussion
— Led by Cheryl Walker, Ph.D., RACGWVI Chair.
Dr. Walker led the committee discussion session. She presented her vision for the 2023 RACGWVI: To guide research for evidence-based decision making by the VA to improve Veterans' health, attract and retain high quality investigators, and support a culture of professionalism, collaboration and accountability that advance ORD Strategic Priorities. Dr. Walker also developed several new subcommittees that had been discussed earlier in the meetings. The purpose of each subcommittee is to provide guidance to the parent committee in its recommendations to the SECVA. Dr. Walker emphasized that the listed/described subcommittees were only tentative, and she was open to redefining them. Subcommittee one will deal with maximizing VA resources to accelerate research. Subcommittee 1A will focus on Human Resources and Veteran engagement such as the Partner Research Program, and 1B will focus on data and biospecimen resources. Subcommittee 2 will focus on advancing intergenerational effects of military exposures.
Tom Mathers**:** Is that a good use of our resources?

Cheryl Walker: That subcommittee can reassess if they choose to, but that research is always discussed at meetings and therefore worthy of our time. Subcommittee 3 will review new data capturing approaches other than IOM. Subcommittee 4 will review heath care effectiveness and integration of new advances, such as ILER; they will also explore the feasibility of VA GWI specialty clinics. Subcommittee 5 will examine specific research topics such as sleep apnea.
The committee members then decided which subcommittees they wanted to serve on and determine who will be the lead for that subcommittee.
Tom Mathers: The research topics should be included in research topics and those research topics should be reviewed for level of priority.
Cheryl Walker: That is a good idea. Since there are no sleep apnea SME as part of the committee, we should also treat some of those topics as a literature review. How does the committee feel about moving research topics?
General Response: All agree.
Ron Brown: Will the VA share with the committee how their process on how they evaluate research; something to keep the committee from reinventing the wheel, so to speak?
Karen Block: That is a new process being developed by the VA and is not in use.
Tom Mathers: I suggest combining 2 and 5.
Cheryl Walker: Concurs, subcommittees 2 and 5 are now the new subcommittee 4.
Tom Mathers: Regarding the new subcommittee 4, will we have enough experience/knowledge to be able to navigate the VA system?
Ken Ramos/Cheryl Walker/Drew Helmer: [all speaking in agreement] Yes, we have over 20 years of working in and navigating the VA system. Also, non-VA people will gain knowledge of the VA system, which will allow a view into the VA clinical research dynamic and process.
James Woody: The maximizing of VA resources and addressing healthcare and effective research will impact all Veterans and improve all Veteran care.
James Woody: Dr. Peter Rumm has developed several various presumptive conditions and should be included in these decisions.
Cheryl Walker: No one seems to be interested in subcommittee 3 (data capture alternatives). Should we remove it?
Drew Helmer: That is an umbrella approach to specific research topics.
Ron Brown: Those reports were what I was trying to refer to in previous discussion, about how information is chosen and what happens to it.
Tom Mathers: Group 3 should be added to the Research Topics bucket.
Bill Watts: A GWV mentioned in the chat to look at myocardial ischemia.
Tom Mathers: I suggest that group develop a laundry list of research items and then decide based on GWI needs and symptom severity to develop a list of priorities.
Karen Block/Cheryl Walker: Confirming with LaTonya Small that subcommittee members are allowed to engage non-committee SME according to FACA guidelines.
Cheryl Walker: Thank you all. We will now move to public comments.

Session 9: Public Comment

— Visitors and Invited Guests

Ken Ramos: Opened the public comments and introduced Bill Watts as moderator.
Bill Watts reading from questions/comments from Chat.
Chat: The committee should investigate GWV and CPAP use and if it is possible to get that information from the VA.
Tom Mathers: What is the overall problem regarding all Veterans and sleep apnea. What is the question we are trying to solve?

Ron Brown: We are trying to link sleep apnea to a service-related issue using evidence-based research to establish a service-related connection to the problem.
Tom Mathers: Are you trying to show a direct connection between Veteran sleep apnea and service in the Southwest Asia theater of operations? Or is it to better treat the GWV with the problem?
Ron Brown: Yes, to both. Service connection means better VA care.
James Woody: Is there a difference between GW service-related sleep apnea and normal population sleep apnea?
Ron Brown: Unknown.
Tom Mathers: That is a great question to start with to lead the research.
Male GWV: [asked the CPAP question] There is a higher incidence of occurrence of sleep apnea in GWV over OIF and OEF Veterans. That data supports GWV had a higher incident of exposures. Specifically addressing the CPAP machine, those machines record information, and the VA has it. The GWV also feels part of that information would support the higher incident of CFS in GWV because they are sleeping longer and more frequently. The GWV presented a well detailed study plan starting at a local VA, then based on the results, could be expanded out to other VA centers and then country wide.
Tom Mathers: The first question asked should be is there a difference between GWV sleep apnea and normal sleep apnea.
Cheryl Walker: Concur.
Ron Brown: Who or how do we contact to get that CPAP information.
Karen Block: That will be for the subcommittee. We should return to public comments.
Chat: Female GWV was told by her specialist that the anthrax and smallpox vaccines caused her multisymptom illness. The SECVA needs to understand the need to research vaccine injury.
Tom Mathers: There is a large body of public knowledge regarding vaccine use and safety, and it is certainly a topic that can be addressed by the subcommittees.
Drew Helmer: Concurs.
James Baraniuk: Vaccine safety was reviewed by multiple sources. Ken
Ramos: We should refrain from addressing specific health issues. Chat:
Are there any studies involving gut health and oral decay?
Chat: Female GWV wants increased recruitment of women Veterans for studies.
Chat: There needs to be an ICD code for GWI.
Chat: When will GWI research start for children of GWV?
Cheryl Walker: That will be part of one of the new subcommittees.
Bill Watts: Since there are no further questions or comments from GWV for this public comment session, we will move to an administrative session.
Cheryl Walker: Thanked all the Veterans for joining the meeting, the speakers for their presentation and closed the meeting to the public and moved it to a private administrative session.

Meeting adjourned.

Acronym List

Acronym	Name
ACOS	Associate Chief of Staff
AE	Adverse Event
Alt-DFO	Alternate Designated Federal Officer
BBRAIN	Boston Biorepository, Recruitment & Integrated Network for GWI
CBA	Capabilities-based Assessment
CDC	Center for Disease Control and Prevention
CDMRP	Congressionally Directed Medical Research Program
CEM	Comprehensive Exposure Monitoring
CFS	Chronic Fatigue Syndrome
CMI	Chronic Multisymptom Illness
COVID-19	Coronavirus Disease Of 2019
CPAP	Continuous Positive Airway Pressure
CRADO	Chief Research and Development Officer
DARPA	Defense Advanced Research Projects Agency
DFO	Designated Federal Officer
dbGaP	database of Genotypes and Phenotypes
DOD	Department of Defense
DOE	Department of Energy
EHR	Electronic Health Record(s)
EMR	Electronic Medical Record(s)
FAC	Federal Advisory Committee
FACA	Federal Advisory Committee Act
GW	Gulf War
GWI	Gulf War Illness
GWV	Gulf War Veteran(s)
GW-MERIC	Gulf War-Military Exposure Research Innovation Center
HIPAA	Health Insurance Portability and Accountability Act
HMRP	Health Monitoring Research Program
HOME	Health Outcomes Military Exposures
HRSA	Health Resources & Services Administrations

HRPO	Health Readiness Policy & Oversight
IEMEWG	Intergenerational Effects of Military Exposures Work Group
ILEAD	Institute for Learning, Education and Development
ILER	Individual Longitudinal Exposure Record
IN-DEPTH	VA-NIH Investigative Deep Phenotyping Study of Gulf War Veteran Health
IOM	Institute of Medicine
IRB	Institutional Review Board
MERIC	Military Exposure Research Innovation Center
MIND	Measures Investigating Neuropsychiatric Disorders
MOU	Memorandum of Understanding
MVP	Million Veteran Program
NAM	National Academy of Medicine
NASEM	National Academies of Sciences, Engineering, and Medicine
NDAA	National Defense Authorization Act
NIH	National Institutes of Health
OEF	Operation Enduring Freedom
OIF	Operation Iraqi Freedom
ORD	Office of Research and Development
PACT Act	The Sergeant First Class Heath Robinson Honoring our Promise to Address Comprehensive Toxics Act of 2022
PEM	Post-Exertional Malaise
PTSD	Post-Traumatic Stress Disorder
QUERI	Quality Enhancement Research Initiative
RAC	Research Advisory Committee
RACGWVI	Research Advisory Committee on Gulf War Veterans' Illnesses
SECVA	Secretary of the VA
SME	Subject Matter Expert
SOP	Standard Operating Procedure
U.S.	United States
VA	Veterans Affairs

VAIRRS	VA Innovation and Research Review System
VBA	Veterans Benefit Administration
VCA	Veterans Care Agreement(s)
VEO	Veteran Experience Office
VES	Veteran Engagement Sessions
VHA	Veterans Health Administration
VINCI	VA Informatics and Computing Infrastructure
WRIISC	War Related Illness and Injury Study Center