



A monthly newsletter dedicated to informing and strengthening the VA Research Community - September 2021

Message from the CRADO

Dear VA Research Community,

Working within the largest integrated health system in the country gives us tremendous opportunities to contribute not only to the lives of Veterans, but also the nation and the world. Pharma and biotech see that capability and want to work with us—as an enterprise—to help advance our strategic priority to increase Veterans' access to high-quality clinical trials.



In March 2020, VA established the [Partnered Research Program](#) (PRP). PRP serves as a research “front door” for external organizations, such as pharmaceutical and biotechnology companies, seeking to conduct high quality multisite clinical trials within the VA health care system. I certainly don't need to tell you that VA is an enormous system! In addition to our clinical facilities, we have 79 dedicated non-profit corporations across the country administering research activities for more than 3,500 VA investigators. These NPCs have administered over \$1 billion in grants—including between \$50 to \$75 million per year in industry-sponsored research—over the last four years. PRP was founded to help industry partners and other external organizations navigate the VA system and to coordinate key processes such as funding, confidentiality agreements, and study site logistics.

Ms. Krissa Caroff has served as the inaugural member and leader of PRP. She has been so successful in her role that we have decided to grow the program. The build-out will include expanding the team, adding new tools to help researchers find partnerships, and enhancing communications and training efforts. If you have questions about PRP, please contact PartneredResearch@va.gov.



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Alongside Krissa, we in central office are keeping our eyes on the evolving landscape of clinical trials. I, myself, have been a guest at the Industry Partner Consortium, which is a group of NPCs and industry partners that have been brought together by the National Association of Veterans' Research and Education Foundations (NAVREF). NAVREF is the professional organization for NPCs. There, I have learned that industry is rapidly shifting to more "virtual" trials, in which the clinical trial is largely brought to the participant. These have been key to keeping clinical trials going in the face of the pandemic. Virtual trials also offer a great opportunity to give even more Veterans access to trials, including those in rural and remote areas. It also will require that we continue to come together as an enterprise so that the policies, processes, and systems are in place to ensure that our research teams are well positioned to lead these trials.

My focus on the research enterprise is grounded in my belief that two of my most important jobs as Chief Research and Development Officer are to (1) improve Veterans' lives through research and (2) to make it as easy as possible for our research teams to accomplish #1. I am honored to serve you as you do your groundbreaking work to serve Veterans.

With gratitude,

Rachel

Rachel Ramoni, DMD, ScD
Chief Research and Development Officer (14RD)
Department of Veterans Affairs



Policy/Admin Updates

ORD approval process for use of proactive calling for subject recruitment—The acting Under Secretary of Health signed [a policy memorandum](#) on June 29, 2021, allowing for the proactive calling of VA subjects, sometimes referred to as "cold calling," as a recruitment strategy for VA human subject research studies using an ORD approval process. Any request for proactive calling for subject recruitment in a VA study must be submitted and approved through this ORD process. ORD approvals are specific to the individual research study submitted with the request. You can view an ORPP&E presentation on proactive calling (8/24/2021) [here](#).

Specific criteria must be met with written justification or description in the request application for the research study:

- The research must be a nonexempt study.
- The research must involve potentially life-saving treatments for a serious disease or condition.
- The research must have a short time window (<96 hours needed to enroll to qualify).

- The application must include justification of why proactive calling must be used instead of using in person or mail notifications as the initial contact.
- The research must describe a verification process for how the serious disease or condition is verified prior to proactively calling the potential subject.
- The research must describe:
 - how the potential subject's primary clinical care team will be contacted prior to the proactive call for study recruitment, or
 - a justification of why the primary clinical care team will not be contacted until after the potential subject has received a proactive call for study recruitment.
- The application must include:
 - a plan to ensure that the calls made by the VA study team are from a non-blocked, VHA number,
 - a copy of the script used for contacting the subject, and
 - the number of calls to be made for each potential subject.
- The application must describe how the telephone numbers will be obtained (e.g., source).
- If the study proposes to leave a message on the potential subject's phone:
 - a script of the proposed message must be submitted with the application, and
 - a plan of steps to be taken to ensure that any message does not include Protected Health Information.

Note: Calling potential VA subjects without first sending a notification in person or through mail or email for the purpose of VA research recruitment is NOT permitted outside of this ORD approval process unless there is written documentation that the subject is willing to be contacted by telephone about the study in question or a specific kind of research as outlined in the study, as per VHA Office of Research and Development (ORD) policy in [VHA Directive 1200.05](#), Requirements for the Protection of Human Subjects in Research.

ORD will have a SharePoint Request Portal in place Monday, Oct. 18.

DocuSign Enterprise License Agreement—In February 2021, the VA Office of Information & Technology (OIT) established a DocuSign Enterprise License Agreement for improving and streamlining the patient experience by eliminating the burden of paperwork on our Veterans.

ORD has leveraged this contract to support researchers in the consent and HIPAA Authorization process.

DocuSign goes beyond the capture of legally binding signature and optimizes:

- **Data Quality:** Deliver accurate and complete form submissions by leveraging data and field validation. Data and field validation ensure accurate and complete form submissions.

- **Self-Service:** Serve the Veteran anywhere, anytime and on any device.
- **Veteran Outcomes:** Deploy, route, and receive forms in days versus weeks/months.
- **Automated Workflows:** Remove the need for manual workflow—download, print, sign, mail, scan, and fax important documents.

By taking advantage of this licensing agreement, ORD has the opportunity to ensure that all forms are digitized, properly completed, and securely stored with the DocuSign Agreement Cloud. This investment also reduces VHA cycle times by eliminating wet signature requirements, and supports FDA requirements for drug and device research studies.

To apply to use this service for your research study, complete a request at [DocuSign Requests - Home \(sharepoint.com\)](#)

VAIRRS News

Below are updates concerning the VA Innovation and Research Review System (VAIRRS).

Collaborative Institutional Training Initiative integration update—As of Sept. 7, 2021, VAIRRS has implemented CITI integration across 101 different research programs. Researchers at those sites can now link their IRBNet profiles to CITI so that their training completed in VA will get pulled in and automatically accepted on a nightly basis. Please refer to the "[Link to CITI Account](#)" guide located on the VAIRRS SharePoint site for further details. Research offices at those sites are being notified via email, including the guide's delivery.

VAIRRS Wizard Completion Campaign—The deadline for study teams to complete the Project Cover Sheet and IRB Information Sheet Wizards for all active projects is Dec. 15, 2021. Please submit your Wizards as soon as possible.

All active research programs have onboarded to IRBNet. The VAIRRS implementation phase is now complete. The next phase will ensure we have a comprehensive data set to power the VHA Research Dashboards. The goal of the dashboards is to leverage the IRBNet enterprise data set to provide ORD leadership and the research community with a complete and accurate representation of VHA research activity.



Resources and Opportunities

Research in Action call for submissions—All VA research is intended to ultimately contribute to the health and well-being of Veterans. VA [Research in Action](#) highlights examples of how VA research has been translated into everyday health care within VHA or in medical care generally.

We are looking for VA projects to highlight that have had substantial, lasting impact on health care across the country and globe. If you know of a VA accomplishment that you think would be a good candidate for this feature, please contact Tristan.horrom@va.gov with details.



Identity Insights participation—VA strives to provide easy, effective, equitable, and emotionally resonant experiences for employees across their workforce lifecycle. We recognize that employees' identities can and will play a role in how they experience VA.

In response, the Veterans Experience Office and the Office of Resolution Management, Diversity & Inclusion have partnered to deploy an intersectional approach to examining and improving the employee experience at VA.

The Identity Insights project will include conducting interviews and focus groups to identify employees' pain points, needs, and challenges, beginning with those in eight identity groups: American Indian and Alaska Native, Asian American and Pacific Islander, Black/African American, Hispanic, individuals born between 1946 and 1964, individuals with disabilities, LGBTQ+, and women.

The Department is committed to ensuring that every employee can bring their authentic self to work and feels a sense of belonging throughout their journey at VA. Please email vaex@va.gov with any questions you might have. [Take the survey](#) for the opportunity to participate in an interview or focus group.

John D. Chase Award nomination deadline—The nomination deadline for the VHA John D. Chase Award for Executive Excellence in Health Care and the 2022 [AMSUS](#) Award program is **Oct. 4, 2021**.

The VHA John D. Chase Award for Executive Excellence in Health Care is a VHA award for sustained executive leadership by an individual from any health care discipline. Fill out a [nomination packet](#) to nominate someone. Once the packet is complete, please send to Caroline.Johnson3@va.gov or Elizabeth.Ruschmeier@va.gov.

Nominations may also be submitted for any of the multiple other AMSUS awards. The nomination process takes place electronically on the [AMSUS website](#). The categories of the other AMSUS awards include:

- **AMSUS Premier Awards:**
 - *Innovator Award*
 - *Rising Star*
 - *Lifetime Achievement*
- **Individual Professional Awards:**
 - *Physician Award*

- *Dentist Award*
- *Nursing Award*
- *Andrew Craige Allied Health Professional Award*
- *Management & Administration Award*
- **Functional Mission Awards:**
 - *Communication Award – new for 2022*
 - *William Gorgas Preventive Medicine Award*
 - *Research & Development Award*
 - *Training & Education Award*

Awards will be presented at the AMSUS Annual Meeting, Feb. 7-10, 2022, at the Gaylord National Resort and Convention Center in National Harbor, Maryland.

Machine learning and applied AI interest group—A new interest group is forming for researchers interested in machine and deep learning, artificial intelligence, neural networks, natural language processing, data science, computer vision, and more. The group plans to host meetings, share research via presentations, share ideas and suggestions, find collaborators to work with, and learn from each other.

The group can be found by searching Microsoft Teams for “**Rockies-Machine Learning and Applied AI.**” Click the link to join, and the group leads will approve your request. *Rockies* is VA’s data and analytics platform built on the cloud through Microsoft Azure. The Rockies proposed purpose when recently formed—after a Request for Information proposal was circulated—is to augment researchers’ work, specifically, to assist VA researchers by “*easing the burden of data access, integration, and organization while enabling a heterogenous ecosystem for data analytics in the VA.*”

For questions about the group, please contact Nathan Walk at Nathan.walk@va.gov.

QUERI Initiative to Advance Diversity in Implementation Leadership—HSR&D/ORD’s Quality Enhancement Research Initiative (QUERI) is launching new funding opportunities that support ORD’s goal of enhancing the real-world impact of research. The [QUERI initiative to Advance Diversity in Implementation Leadership \(ADIL\)](#) promotes implementation leadership opportunities with the ultimate goal of growing a pipeline of implementation and evaluation expertise from populations that reflect the diversity of the Veterans VA serves and transforming Veteran care, especially for underserved and marginalized populations. QUERI is also soliciting applications to set up Evidence-based Policy Evaluation Centers to conduct rigorous, independent evaluations focused on national priorities that are informed by the Foundations for Evidence-based Policymaking Act. Check out the [ORD RFA website](#) (after Sept. 30) for more details and a cyberseminar discussing the EBP Center RFA will be held on Sept. 16 at 2 pm ET – register using [this link](#).

QUERI Implementation Science Learning Opportunities—All VA employees have the power to make health care better for Veterans and their families. QUERI’s learning hubs provide a unique opportunity for leaders, providers, and researchers across VA to gain the practical experience and skills needed to accelerate the implementation of research findings into clinical practice and lead care improvements at their sites. Check out the

[QUERI website](#) for more information on implementation and quality improvement training opportunities or contact the QUERI Center for Evaluation and Implementation Resources (CEIR) at ceir@va.gov.

Veterans' Perspectives newsletter—HSR&D's monthly publication *Veterans' Perspectives* highlights research conducted by HSR&D and/or QUERI investigators, showcasing the importance of research for Veterans—and the importance of Veterans for research. Read the latest issue [here](#).

Employment

- (09/10/21) [Health Sciences Research Coordinator, EPIC³Study](#) - Seattle, WA
- (09/10/21) [Research Program Manager](#)- Seattle, WA
- (09/09/21) [Health Science Specialist \(Research Study Coordinator\)](#)- Orlando, FL
- (09/08/21) [Administrative Officer](#)- Salem, VA
- (09/07/21) [Tenure-Track or Tenured Faculty Position in Health Policy at the Assistant or Associate Level](#)- Los Angeles, CA
- (08/24/21) [Study Coordinator](#)- Portland, OR
- (08/23/21) [Health Sciences Research Assistant/Research Specialist](#)- Seattle, WA
- (08/13/21) [Program Manager](#)- Boston, MA
- (08/13/21) [National Program Coordinator](#)- Boston, MA
- (08/13/21) [Project Manager/Business Analyst](#)- Boston, MA
- (08/13/21) [Deputy Director - Million Veteran Program](#)- Boston, MA
- (08/12/21) [Research Assistant](#)- Pittsburgh, PA
- (08/11/21) [Clinical Research Regulatory Specialist](#)- Providence, RI

More VA Research opportunities can be seen on the [ORD website](#). Members of the VA Research community who are interested in advertising their available positions here can submit requests to ORD.Web@va.gov.



Noteworthy Publications

Below is a small sampling of noteworthy studies published by VA researchers within the past month. This list is intended to reflect the broad spectrum of VA research, but is in no way inclusive of all VA researcher topics or projects. Visit the [VACO Library](#) website to sign up for alerts on published VA studies on many different topics.

[Recurrence of colorectal neoplastic polyps after incomplete resection.](#) Pohl H, Anderson JC, Aguilera-Fish A, Calderwood AH, Mackenzie TA, Robertson DJ. This natural history study found a statistically significantly greater risk for future neoplasia and advanced neoplasia in colon segments after incomplete resection compared with segments with complete resection. *Annals of Internal Medicine*. 2021 Aug 10. Online ahead of print.

[Does this adult patient have hypertension?: The rational clinical examination systemic review.](#) Viera AJ, Yano Y, Lin FC, Smel DL, Yun J, Dave G, Holle AV et al. Office measurement of blood pressure may not be accurate enough to rule in or rule out hypertension; home blood pressure monitoring may be helpful to confirm a diagnosis. *JAMA*. 2021 Jul 27;326(4):339-347.

[Medication adherence in cardiovascular medicine.](#) Simon ST, Kini V, Levy AE, Ho PM. This review examines a variety of strategies to improve medication adherence that have been tested in clinical trials. *BMJ*. 2021 Aug 11;374:n1493.

[Population sequencing data reveal a compendium of mutational processes in the human germ line.](#) Seplyarskiy VB, Soldatov RA, Koch E, McGinty RJ, Goldmann JM, Hernandez RD, Barnes K et al. Researchers identify a mutagenic effect of active demethylation primarily acting in regulatory regions and a mutagenic effect of long interspersed nuclear elements. *Science*. 2021 Aug 27;373(6558):1030-1035.

[Association between administration of IL-6 antagonists and mortality among patients hospitalized for COVID-19: A meta-analysis.](#) Shankar-Hari M, Vale CL, Godolphin PJ, Fisher D, Higgins JPT, Spiga F, Savovic J et al. Administration of IL-6 antagonists, compared with usual care or placebo, was associated with lower 28-day all-cause mortality from COVID-19. *JAMA*. 2021 Aug 10;326(6):499-518.

[Empagliflozin in heart failure with a preserved ejection fraction.](#) Anker SD, Butler J, Filippatos G, Ferreira JP, Bocchi E, Böhm M, Brunner-La Rocca HP et al. Empagliflozin reduced the combined risk of cardiovascular death or hospitalization from heart failure in patients with heart failure and a preserved ejection fraction, regardless of the presence or absence of diabetes. *New England Journal of Medicine*. 2021 Aug 27. Online ahead of print.

[Cardiovascular events with finerenone in kidney disease and type 2 diabetes.](#) Pitt B, Filippatos G, Agarwal R, Anker SD, Bakris GL, Rossing P, Joseph A et al. Among patients with type 2 diabetes and stage 2 to 4 chronic kidney disease with moderately elevated albuminuria or stage 1 or 2 CKD with severely elevated albuminuria, finerenone therapy improved cardiovascular outcomes as compared with placebo. *New England Journal of Medicine*. 2021 Aug 28. Online ahead of print.

[Haemodynamic-guided management of heart failure \(GUIDE-HF\): a randomised controlled trial.](#) Lindenfeld J, Zile MR, Desai AS, Bhatt K, Ducharme A, Horstmanshof D, Krim SR et al. Hemodynamic-guided management of heart failure did not result in a lower composite endpoint rate of mortality and total heart failure events compared with a control group. *Lancet*. 2021 Sep 11;398(10304):991-1001.



Media Buzz

Social Media Highlights

On Aug. 16, the main VA Twitter account tweeted to its over 600,000 followers a story about women leaders across VA joining the Million Veteran Program.



Veterans Affairs  @DeptVetAffairs · Aug 16



Women leaders across VA enrolled in a national research program looking at health and illness in Veterans. They invite you to join them.



VA women leaders join women Veterans in research | Vantage Point
Women leaders across VA enrolled in a national research program looking at health and illness in Veterans. They invite you to join them.
blogs.va.gov

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On July 17, VA tweeted about the STARPORT trial, which examines innovative treatment for prostate cancer.



Veterans Affairs @DeptVetAffairs · Aug 17

A VA study is examining an innovative treatment for men whose prostate cancer has spread to distant areas despite surgery or radiation.



'STARPORT' trial probes new approach for aggressive prostate cancer...
A VA study is examining an innovative treatment for men whose prostate cancer has spread to distant areas despite surgery or ...
blogs.va.gov

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If you would like to submit a post to go on the VA Research Facebook, Twitter, or Instagram pages, please do so via email at ORDMedia@va.gov.

Please include the following information:

- Desired platform: Facebook, Twitter (240 character max), or Instagram
- Post content
- Image
- Link

After the above are submitted, the request will be forwarded to the ORD Communications team for approval and scheduling. Posts may also be added to a library of potential stories to be picked up by other VA social media accounts, such as the main VA pages.

VA research in the news

Study: COVID-19 may cause long-term kidney damage

Multiple news outlets reported on a [new study](#) in the *Journal of the American Society of Nephrology*, led by Dr. Ziyad Al-Aly at the St. Louis VA, that is related to a [broader study](#) on long COVID published by the same group in the journal *Nature* earlier this year.

According to the *New York Times*, the new study “suggests that kidney issues can last for months after patients recover from the initial infection, and may lead to a serious lifelong reduction of kidney function in some patients. The study ... found that the sicker Covid patients were initially, the more likely they were to experience lingering kidney damage. But even people with less severe initial infections could be vulnerable.”

The group analyzed VA data on 89,216 people who tested positive for the virus between March 1, 2020, and March 15, 2021, and more than 1.6M controls. “People who have survived the first 30 days of Covid are at risk of developing kidney disease,” said Dr. Al-Aly. He added, “What’s really important is that people realize that the risk is there and that physicians caring for post-Covid patients really pay attention to kidney function and disease.” According to the NYT, “The study is the largest study so far on Covid-related kidney problems.”

The *New York Times*, *Bloomberg*, *U.S. News & World Report*, *MSN* and other media outlets reported on the study.

Research Photo of the Month



Researchers at the VA New England Healthcare System are studying how repetitive head impacts can damage the brain and lead to chronic traumatic encephalopathy and Alzheimer’s disease. *Photo by Frank Curran.*

Do you have photos of VA researchers in action or interesting science images from your lab? Share them with us! Send you photos to *ORD Field Update* editor Tristan Horrom at tristan.horrom@va.gov.



Upcoming Events

The next ORD Monthly Field Call will be held on **Sept. 20, 2021**, at 1:30 EST on Microsoft Teams.



Achievements and Milestones

We are looking for VA researchers who served in the military to feature in a series called [VA Researchers Who Served](#). The profiles explain the critical work that VA researchers do for the Veteran community and at the same time highlight and recognize their military service.

If you know a VA researcher who would be a good candidate for this series, please contact Mike Richman (Michael.richman1@va.gov).

Awards

Dr. Louis Dell'Italia named 2021 Barnwell Award winner—CSR&D is proud to announce the 2021 John B. Barnwell Award winner is Dr. Louis J. Dell'Italia from the Birmingham VA. The Barnwell Award is the Clinical Science Research and Development Service's highest honor for outstanding achievement in clinical research that advances the diagnosis, prevention, and/or treatment of diseases and disorders in the Veteran population.

Dr. Dell'Italia's scientific leadership and his commitment to improving health care for Veterans are clearly reflected in his outcomes-based clinical trials that have changed clinical practice for millions of patients. His dedication and service to VA is apparent by his role of associate chief of staff for research for over 12 years. He has seven Top 10 Teaching Excellence Awards in the Departments of Medicine of the University of Alabama at Birmingham (UAB) and University of Texas at San Antonio and for the UAB Dean's Mentorship Award. Dr. Dell'Italia is a dedicated VA physician-scientist with over 32 years of service.

Dr. Dell'Italia began his VA career as a physician in San Antonio. In 1989 he joined the staff of Birmingham VAMC. His research contributions to clinical science has been focused in three areas: right ventricle, mitral regurgitation, and the renin angiotensin chymase system. In each area he has pursued novel approaches that have had significant clinical impact.

Career Milestones



ORD names Liza Catucci acting director of operations—Liza M. Catucci, MPH, was appointed acting director of operations for the ORD on August 29, 2021. In her role as acting director, Liza will advise and support the CRADO and the deputy CRADO in the planning, development, and operations of all VA research programs. She will provide programmatic coordination among the services and oversight of administration and scientific review.

Liza served as chief operating officer for Health Services Research and Development (HSR&D) in ORD beginning in August 2014. Prior to joining HSR&D, she served as administrative officer for Clinical Science Research, and director of operations for the Human Research Protection Program at the VA Boston Healthcare System.

Liza joined VA in 1993 after leaving her position as administrator for the cardiovascular research department at the New England Regional Primate Research Center/Harvard Medical School. From 2005 to 2006 she spent a sabbatical year as the health systems specialist to the West Palm Beach VAMC director and oversaw the Office of Patient Advocacy, coordinated the Graduate Healthcare Administration Training Program (GHATP), provided consultation to leadership on the requirements for re-establishing a clinical science/human subject research program infrastructure, and concurrently served as the facility public affairs officer.

Liza completed a bachelor's degree in biology at RI College where she conducted recombinant DNA research with HeLa cells to identify origins of replication on Okazaki fragments. In 2019 Liza received a Master of Public Health from The Dartmouth Institute for Health Policy and Clinical Practice in the Geisel School of Medicine. At Dartmouth, she was named a TDI Pioneer Scholar and received a special commendation for her research practicum on misdiagnosis of chronic obstructive pulmonary disease. Liza remains engaged with Dartmouth as a teaching assistant in the MPH Hybrid Program.

History Corner



Demonstrating the risk of high blood pressure—In 1971, Army Veteran and VA researcher Dr. Edward Freis received a Lasker Award for his “exemplary demonstration of the potential of preventive medicine.” Before Freis’s work, most physicians did not understand that high blood pressure, except in extreme cases, was a problem for their patients. The trial that Freis led through VA’s Cooperative Studies Program showed otherwise, and would help save many people from falling victim to strokes or other complications of high blood pressure. The study, which ran from 1964 through 1969, was one of the first randomized, placebo-controlled, double-blind, multisite clinical trials in the United States, with 523 patients and 17 VA sites participating.

Anyone interested in receiving general news updates about VA research is invited to [sign up](#) for our VA Research Currents and VA Research Spotlight monthly emails.



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