VA St. Louis Health Care System Research and Development Service Research Day 2023



U.S. Department of Veterans Affairs

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The VA St. Louis Health Care System

The VA St. Louis Health Care System (VASTLHCS) is a full-service health care facility providing inpatient and ambulatory care in medicine, surgery, psychiatry, neurology, and rehabilitation, as well as over 65 subspecialty areas. It is a two-division facility that serves Veterans and their families in east central Missouri and southwestern Illinois.



John Cochran Division 915 North Grand Blvd., Saint Louis, MO 63106 Phone: 314-652-4100



The John Cochran Division, named after the late Missouri congressman, is located in midtown St. Louis in close proximity to its affiliated medical schools - Saint Louis University and Washington University. It has all of the medical center's operative surgical capabilities, the ambulatory care unit, and a six-story Clinical Addition that includes surgical facilities, intensive care units, outpatient psychiatry clinics, and expanded laboratory.

The Jefferson Barracks Division is a multi-building complex overlooking the Mississippi River in south St. Louis County. It provides psychiatric treatment, regional spinal cord injury treatment, a nursing home care unit, geriatric health care, rehabilitation services, and a rehabilitation domiciliary program for homeless Veterans.

Jefferson Barracks Division #1 Jefferson Barracks Drive, Saint Louis, MO 63125 Phone: 314-652-4100

The VA St. Louis Health Care System is associated with the following Community Based Outpatient Clinics (CBOCs)

- Franklin County VA Clinic, Washington, MO
- Manchester Avenue VA Clinic, St. Louis, MO
- Olive Street VA Clinic, St. Louis MO
- St. Charles County VA Clinic, O'Fallon, MO
- St. Clair County VA Clinic, Shiloh, IL
- St. Louis County VA Clinic, Florissant, MO
- Washington Avenue VA Clinic, St. Louis, MO

VA Research & Development Program An Enduring Commitment to Veterans



Ziyad Al-Aly, M.D., FASN

For more than 95 years, Veterans Affairs (VA) Research has advanced beyond anything early VA researchers could have imagined. VA Research is designed to directly address the health issues affecting Veterans and improve their lives in tangible and significant ways. It also affects the lives of all Americans through health care discovery and innovation.

VA Research is unique because of its focus on health issues that affect Veterans. It is a part of an integrated health care system with a state-of the art electronic health record and has come to be viewed as a model for superior bench-to-bedside research. Our research deals with many current topics that are critical to today's Veterans including the following: the chronic effects of neurotrauma; VA's Million Veteran Program (genomics); pain and opioid research; PTSD; prosthetics; rehabilitation engineering; spinal cord injury; suicide prevention; traumatic brain injury (TBI); VA clinical trials; Vietnam Veterans' research and female Veterans' research.

VA Research fosters dynamic collaborations with academia, other federal agencies, non-profit organizations, and private industry, thus furthering the program's impact on the health of Veterans and the nation.

We hope this booklet gives you an overview of our St. Louis VA Research Program and an understanding of the scope and impact of the work being done by talented, dedicated investigators at the St. Louis VA. Thanks to their brilliant efforts and the many Veterans who volunteer to take part in VA research, we proudly carry forth our long-standing tradition of discovery, innovation and advancement.

Sincerely,

Ziyad Al-Aly, M.D., FASN Associate Chief of Staff Research Service

VA St. Louis Health Care System Research and Development Service 501 North Grand Blvd. St. Louis, MO 63103 314-289-6333

Introduction

VA Research fosters dynamic collaborations with its university partners, other federal agencies, nonprofit organizations, and private industry — thus furthering the program's impact on the health of Veterans and the nation.

The VA St. Louis Health Care System (VASTLHCS) Research and Development Service supports VA investigators by working with them to develop health-related research applications within an area that is relevant to the care of Veterans. Research funding is awarded to VA medical centers on behalf of principal investigators to facilitate the pursuit of a scientific objective. VA Office of Research and Development (ORD) issues targeted funding opportunity announcements (FOAs) and requests for applications (RFAs) for research addressing specific Veterans' health care issues.

Our VA Program is unique in that it is the only research program focused on conducting pioneering research to meet the full scope of Veterans' medical needs.

It has become an admired model for conducting the highest quality of research. VA research not only benefits Veterans but improves healthcare to the entire nation through innovation and discovery.

Our Research Program in St. Louis has approximately 125 active studies. We reported approximately \$4.5M in annual spending in FY22. Our Program continues to attract the best and brightest researchers, most of whom are VA clinicians and are able to promote the rapid translation of research findings into advancements in care. We continue to embrace continuous improvement, working closely with the VA Office of Research and Development (ORD) and Office of Research Oversight (ORO) to adopt best practices seen across the VHA research enterprise. Our administrative staff brings these best practices to our Subcommittees to help improve efficiency in our processes and quality of outcomes for the Veterans we serve.

The research process in VA starts with a tight focus on the everyday health needs and concerns of Veterans, and with consultation with national and regional VA clinical leaders. Solutions are identified and developed through careful, rigorous research in labs and clinics, and sometimes in the community. These solutions are then applied to patient care, or translated into new or improved programs, as rapidly as possible.

Requests for Applications (RFAs) are the appropriate mechanism for investigator-initiated VA research. The Merit Review Award Program is an intramural funding mechanism to support investigator-initiated research conducted by eligible VA-ORD investigators at VA medical centers (VAMCs) or VA-approved sites.

• Our investigators submitted over 20 Merit Review Award applications in 2022 to the Biological Laboratory Research & Development, Clinical Science Research & Development and Health Service Research & Development Services.

Veterans Health Administration Office of Research and Development Program Services

The Office of Research and Development (ORD) consists of four research services that together form a cohesive whole to explore all phases of Veterans' health care needs. Each service oversees a number of research centers of excellence.

Each of these four services is headed by a director who is supervised by the Chief Research and Development Officer (CRADO), who in turn reports to the Deputy Under Secretary for Health for Policy and Services. The four services are listed below with a brief description.

The <u>Biomedical Laboratory Research & Development Service</u> (BLR&D) conducts research that explores basic biological or physiological principles in humans or animals but does not involve intact human beings. For example, it includes research on animal models and investigations of tissues, blood or other biologic specimens from humans.

The <u>Clinical Science Research and Development Service</u> (CSR&D) conducts research that focuses on intact human beings as the unit of examination. Examples include interventional and effectiveness studies, clinical, epidemiological and technological studies.

The <u>Health Services Research and Development Service</u> (HSR&D) pursues research at the interface of health care systems, patients and health care outcomes. HSR&D underscores all aspects of VA health care; specifically, quality, access, patient outcomes and health care costs.

The <u>Rehabilitation Research & Development Service</u> (RR&D) is dedicated to the well-being of America's Veterans through a full spectrum of research: from approved rehabilitation research projects, through evaluation and technology transfer to final clinical application.

Overview of Research Awards, Budget Caps and Duration:

Merit Review Awards

BLR&D & CSR&D: \$165K/yr, yr1 -yr4 HSR&D: \$1.2M / maximum 4 yrs RR&D: \$1.2M / maximum 4 yrs Research Career Development Awards BLR&D & CSR&D: PI salary support & \$105K/yr1 - \$75K/yr, yr2 – yr5. HSR&D: PI salary support & \$40K/yr, yr1 – yr3 RR&D PI salary support & \$75K/yr, yr1 - yr5

All current VHA ORD Requests for Applications (RFAs) can be found on the VA <u>intranet</u> at <u>RFA's and Program Announcements</u> or by contacting Todd Kliche, Research Service Grants Manager at <u>todd.kliche@va.gov</u>.

The VA Research and Development Program is an intramural program to fund research conducted by VA-salaried investigators at VAMCs or VA-approved sites, managed at the highest level by the VHA Office of Research and Development (ORD). A Principal Investigator (PI) shall hold an MD, PhD, or equivalent doctoral degree in a medical, biological, or behavioral science field.

All PIs must have a VA paid appointment of at least 25 hours per week (5/8^{ths}) to receive ORD research funding (VHA Handbook 1200.15) through a VA grant mechanism. The VA employment status of each PI must be indicated in the grant application. If a clinician PI does not have a current, 5/8^{ths} VA paid appointment then a Director's Letter of Support from the Medical Center Director must include a commitment to offer the PI at least a 5/8^{ths} VA paid appointment at the VAMC. This is conditional upon approval of the grant application for funding.

Alternatively, eligible Pl's may apply to the ORD Career Development Program (VHA Program Guide 1200.04). The Career Development Award (CDA) was established to mentor junior researchers, so they can learn from renowned, experienced VA researchers. Each of the 4 ORD Services offers a CDA program. Once accepted into the CDA program, through the Letter of Intent process, PIs may apply to specific RFAs which provide salary support in additional to funding for the research proposal.

In addition, ORD provides support to non-clinicians through the Research Career Scientist Program (VHA Program Guide 1200.20). Recognizing the importance of non-clinician researchers in improving the care of Veterans, ORD offers a process for qualified individuals who have a PhD in a medical, biological, or behavioral science field.

Information on all of the forementioned programs is available by contacting Todd Kliche, Research Service Grants Manager at todd.kliche@va.gov.

St. Louis Veterans Research and Education Foundation



The St. Louis Veterans Research and Education Foundation (VREF) has worked diligently alongside the VA St. Louis Health Care System since 1994. This relationship has resulted in astounding research outcomes and data on Veteran centric care. One such example of those results was clearly evidenced by the SPRINT study. This study had such an impact that the NIH chose to publish early results which alerted doctors to change treatment protocols for all patients with high blood pressure.

The VREF portfolio has continued to grow at an incredible pace each year and is the portal for applications for grants and projects outside of the VA to which a PI may apply. VREF also works

closely with the medical and pharmaceutical industry who offer clinical trials that clearly add benefit to the care of Veterans.

VREF is currently administering 38 active research projects with 31 occurring at St. Louis VA Clinical Trials Unit (CTU). This work is possible due to the strong support provided to the Foundation from the VA St. Louis Health Care System and specifically Dr. Al-Aly's staff within the Research and Development Service.

More information regarding VREF research opportunities, events to attend or ways to donate can be located at:

- Facebook <u>www.facebook.com/VREFSTL</u>
- Instagram @veteransresearch
- Twitter @VREFSTL
- Website <u>www.vrefstl.org</u>
- Or by contacting Allison Shafer, VREF Executive Officer at <u>Allison.Shafer@va.gov</u>

Donate Now! - Veterans Research and Education Foundation of St Louis (vrefstl.org)

Veterans Research & Education Foundation 501 N. Grand Boulevard Suite 300 St. Louis, Missouri 63103

VA St. Louis Health Care System, Research and Development Service Leadership Team

Dr. Ziyad Al-Aly, M.D., Associate Chief of Staff, Research Service (ACOS/R)

Ziyad.Al-Aly@va.gov

Susan Wood, Administrative Officer, Research Service (AO/R)

Susan.Wood3@va.gov

Kendrick Coleman, Administrative Officer, Research Service Clinical Trials Unit (AO/CTU)

kendrick.coleman@va.gov

Gary Schofield, RN, Research Service Nurse Manager

Gary.Schofield@va.gov

Alysha Hunter, Research Service Management Analyst

Alysha.Hunter@va.gov

Erin Olson, Research Service Budget Analyst

Erin.Olson@va.gov

Todd Kliche, Research Service Grants Manager

Todd.Kliche@va.gov

Research and Development Service Mission Critical Colleagues

Sandy Prosise, Research Compliance Officer (RCO) Sandra.Prosise@va.gov.

Sandy has recently accepted the position of RCO at VASTLHCS. Prior to this she served as the Subcommittee Administrator for our IACUC, SRS and IRB. Her position reports to the ORO through the

Medical Center Director as part of our Quality Management Service. Thus, providing an independent, third-party reviewer of research activities. She brings her operational knowledge of the research enterprise to her new role of ensuring its compliance with all VHA Guidance.

Paige Zimerman, Technology Transfer Specialist Paige.Zimerman@va.gov.

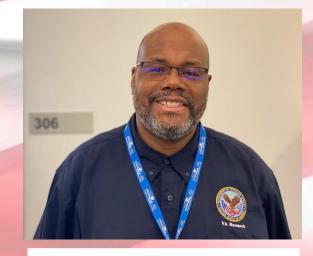
Prior to accepting the position of Field Technology Transfer Specialist, Paige served as the Research Service Management Analyst. Currently Paige reports to the Office of Research and Development (ORD) <u>Technology Transfer Program (TTP)</u> serving all VA medical centers in Missouri and Kansas. The mission of TTP is to facilitate the commercialization of VA technology and inventions to benefit our Nation's Veterans and the American public. TTP strives to achieve this goal by educating VA employees concerning their rights and obligations with respect to the development of technology, evaluating VAdeveloped technology and in turn invention disclosures, applying for intellectual property protection and assisting in the commercialization of new products. TTP has also begun to fund, manage and lead research and development throughout the VA to better commercialize VA-developed technology.



Marie White, RN and Linda Schimmoeller, RN CTU Study Coordinators



Fahreta Hamzabegovic, IRB Administrator

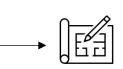


Kendrick Coleman, AO/R CTU

Project Approval Pathway VA St. Louis Health Care System Research Subcommittees



PI received a favorable score for their grant application from ORD and Subsequent Notice of Award (NoA), submits project components to relevant subcommittees.



Institutional Review Board (IRB) serves as the primary reviewer for all projects that involve the use of human subjects as described by the Revised Common Rule and Veterans as described by VHA 1200.05.

Subcommittee Administrators Fahreta Hamzabegovic & Natalie Niceforo (<u>STL.IRB.Admin@va.gov</u>) Chair: Dr. Chandra Reddy, M.D. (Chandra.Reddy@va.gov)

The IRB is currently managing 28 active studies. **Dr. Chandra Reddy, M.D.**, has led the IRB through significant reorganization in 2022 with the additional of several new members creating a highly engaged Board.

The Institutional Animal Care and Use Committee (IACUC) serves as the primary review for all Animal Components of a Research Protocol (ACORP) present in VA approved research.

The Subcommittee for Research Safety (SRS) serves as the primary reviewer for the safety components of all VA approved research occurring on site or at our affiliated medical schools.

Subcommittee Administrator

Erin Torrence (Erin.Torrence@va.gov) Chair: Dr. Jacki Kornbluth, PhD (Jacki.Kornbluth@va.gov)

Dr. Jacki Kornbluth, PhD, continues oversight of the safety aspect of our research studies per VHA 1200.08(1). The SRS reviews reports regarding laboratory inspections, emergency preparedness, biosafety and security, vulnerability assessments, and chemical inventories. This responsibility includes VA research conducted on site as well as those conducted at affiliated universities. Subcommittee Administrator

Erin Torrence (<u>Erin.Torrence@va.gov</u>) Chair: Dr. Marc Levin, M.D. (<u>Marc.Levin2@va.gov</u>)

As the VA St. Louis Health Care System does not operate an animal research facility, Dr. Levin and his subcommittee continue to provide oversight of all VA research involving animals occurring at our affiliated medical schools per VHA 1200.07.



Once informed of the RDC's decision to approve a project, **Dr. Ziyad Al-Aly, ACOS/R&D** will release an ACOS Implementation Memo to the PI authorizing the VA Research to begin.



The Research and Development Committee (RDC) is responsible for final approval of all VA Research which is pursuant to the approval of each component of the project by the relevant subcommittees per VHA 1200.01.

Subcommittee Administrator Denise Garnett (<u>Denise.Garnett@va.gov</u>)

Chair: Dr. Fred Metzger, PhD (Fredric.Metzger@va.gov)

Dr. Fredric Metzger, PhD, continues to oversee the Research Program. In 2022, 23 new human and animal studies were submitted to the RDC for review and approval, along with many continuing reviews. The RDC also works with the VA Central IRB to monitor multi-site studies which are being performed in St. Louis.

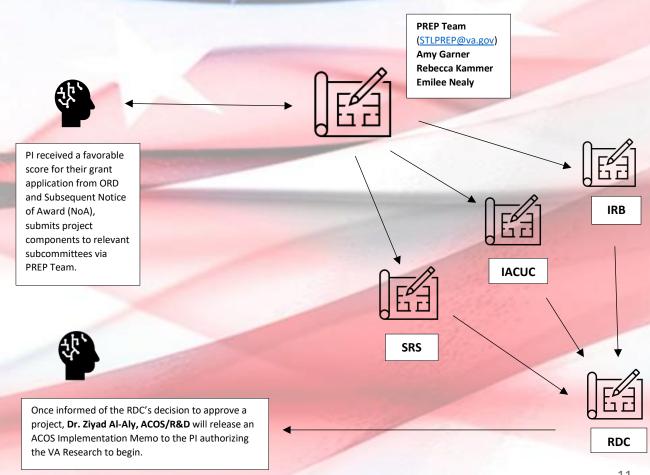
Pre-Review and Education Program: The (PREP) Team

For more than 5 years the PREP Team has helped improve the efficiency of the approval process of VA research at the VA St. Louis Health Care System through their close work with PI's and all of the Research Service Subcommittee Administrators. The process was instituted to aid investigators through regulatory committee submissions and ultimately get studies off the ground more quickly. The goal of the process is fourfold: **1**) assist in study feasibility assessment **2**) guide study teams through the committee application process **3**) identify and assess required resources **4**) provide initial regulatory compliance overview. Investigators are supported through the new study application steps by the PREP Team. The team



Amy Garner, Rebecca Kammer, Emilee Nealy

meets with the investigators early in the submission process to help identify and resolve potential approval and startup barriers and assist teams with committee application forms. The pre-review process has proven to help alleviate study implementation slowdowns, improve regulatory compliance, as well as significantly decrease the timeline of study approvals from start to finish and the administrative workload of the Institutional Review Board. The PREP Team is unique to our Station and has been recognized by ORO and ORD during oversight visits as a best practice.



Secondary Review of VA Approved Research through the "Just in Time" Information Portal

Principal Investigators (PIs) may not commence performance of specific aims of an application selected for funding, until and unless applicable regulatory and other documents are reviewed and approved in the Just in Time (JIT) portal to ensure all VA regulations/policies are met. At a minimum, the PI will be asked to provide a VA Quad Chart which is a single Power Point slide containing several data points regarding the project, the ACORP once approved by VA St. Louis Research Service IACUC and Other Support documentation.

The expectation from ORD to the Station and PI is this process will be completed no more than 180 days from the time it populates in eRA Commons / JIT. Failure to complete this review can result in withdrawal of the Notice of Award. Funds will not be released by ORD until all JIT requests have been adjudicated.



Research Space

It is expected that the PI and VA co-investigators will perform all of the funded research in VA space or VA-leased space. However, if any of the proposed work will be carried out in non-VA space assigned to (or controlled by) a PI or VA investigator, a waiver to perform the research off-site must be obtained prior to submitting the application

Work performed in a non-VA collaborator's off-site laboratory or off-site core facility does not require an off-site research waiver, except when a VA investigator is the core facility director. Guidelines for submitting an application for an off-site research waiver are described in the VHA Handbook 1200.16, VA Off-site Research Handbook. Requests for off-site waivers should be submitted by the due dates listed in the ORD submission calendar.

The VASTLHCS has space for research activities spread across the medical facility. This includes labs and offices at the John Cochran Division in Building 7A and Building 1 on various floors with new offices on floor 9 to be opened soon. Our Research Administration Office is located at 501 North Grand Boulevard, St. Louis, MO, 63103. The VASTLHCS has VA-leased space at Saint Louis University's Doisy Building and VA-approved space in various buildings at Washington University.

Clinical Trials Unit

The St. Louis VA Health Care System's Clinical Trials Unit (CTU) continues to conduct research studies that have contributed to saving and improving the quality of life of our Veterans. Our commitment to the principals of ICARE (Integrity, Commitment, Advocacy, Respect, and Excellence) are reflected in VA Research. Within the CTU, WE CARE about our patients by Welcoming them to our facilities and our Clinical Trials, **E**xplaining who we are and what we do, **C**onnecting with them to know who they are, **A**ctively listening to them, **R**esponding to them with dignity and respect and Expressing gratitude for their service.



Lindsey Vargo, Janine Kampelman RN, Gary Schofield RN, Brittany Minor, Patrice Simpson, and Carley Browning



April Phipps, Study Coordinator

Our Veterans are generous enough to participate in our studies. The clinical trials being conducted in the CTU focus on lung and prostate cancer, spinal cord injuries, gout, diabetes and coronary artery disease, Parkinson's disease, Alzheimer's disease and several other areas of interest. **Kendrick Coleman**, **Administrative Officer (AO) / CTU** (kendrick.coleman@va.gov), currently provides oversight to 34 active studies with 12 more projects in the startup phase occurring in the CTU. Along with Kendrick is **Gary Schofield, R.N., Nurse Manager** (<u>Gary.Schofield@va.gov</u>) who also provides support to an outstanding group of 20 Research Coordinators who are

managing one or more research studies at any given time. Collectively, the CTU holds numerous years of research experience, familiarity with the VA healthcare system, and are dedicated to the care of Veterans.

Notable Research: The CTU continues to demonstrate its flexibility in supporting research activities beyond local VA Research to include themselves as a participating site in numerous multi-site studies sponsored at a Federal level. Since 2021 Dr. Eric Knoche, M.D. has been the Site Principal Investigator for 4 projects managed by the National Institutes of Health, National Cancer Institute Central Institutional Review Board (NCI-CIRB). In 2021 Dr. Ted Thomas, M.D. became the Site Principal Investigator for the Department of Veterans Affairs Lung Precision Oncology Program (LPOP) adding St. Louis to a list of 21 other VA Medical Centers contributing to the advancement of precision oncology. These



Danielle Tate, CTU Program Support Assistant

examples highlight how research conducted at the St. Louis VA is contributing to scientific findings assessed at a national level.

Clinical Epidemiology Center

The Clinical Epidemiology Center (CEC) at the Saint Louis VA Health Care System (VASTLHCS) began its operations in July 2013 thanks to a Department of Veterans Affairs T21 grant. The CEC is a core resource available to VA investigators to support and grow clinical epidemiology research at the VASTLHCS. Since its inception, the CEC has offered seminars organized around topics of interest within clinical epidemiology including lectures on novel concepts in biostatistics, epidemiology, data visualization, presentations of current research results, and hands-on seminars in statistics, grant writing, and proposal preparation.

The Clinical Epidemiology Center has been established to provide investigators working with the St. Louis VA with systematic support in building their research capacity, and in turn, the research capacity of the VA in order to improve the health of Veterans nationwide. It interfaces with the VA Informatics and Computing Infrastructure (VINCI) to produce the following services:

- Research design
- Data analysis
- Results dissemination
- Training and education

<u>Notable Research</u>: In November 2020 Dr. Ziyad Al-Aly, M.D. and his study team leveraged the strength of the CEC in his project leading to the publication of a seminal paper Acute Kidney Injury in a National Cohort of Hospitalized US Veterans with COVID-19. As the novel coronavirus pandemic – 2019 (COVID-19) has progressed, Dr. Al-Aly and his team have published an additional 23 papers on the topic in journals such as Nature, Nature Medicine, and The Journal of the American Medical Association. His work has led to a worldwide collaborative effort to better understand the condition of Long COVID. Dr. Al-Aly's team member Dr. Ulysses Labilles, PhD (Ulysses.Labilles@va.gov) leads a monthly lecture series on the topic providing a stage for subject matter experts to disseminate and discuss their initial findings.



Dr. Ulysses "Uly" Labilles

Checklist for Publishing VA Research

Below are requirements that authors must address when publishing research that was funded by VA or that used VA resources. Much of this information is covered in VHA Handbook 1200.19 – Presentation of Research Results. Note that the ORD service funding the study may have additional requirements; contact the specific service or review the ORD website for more information.

Acknowledge VA support

If the work was funded by VA, include this statement: "This work was supported [or supported in part] by [type of award, e.g., Merit Review, Career Development Award, Pilot Project] Award # [award/project number, e.g., I01 RX000123] from the United States (U.S.) Department of Veterans Affairs [as applicable, indicate Biomedical Laboratory Research and Development Service; Clinical Sciences Research and Development Service (mention the CSR&D Cooperative Studies Program if applicable); Rehabilitation Research and Development Service; or Health Services Research and Development Service]." If VA only provided resources (e.g., facilities or patients), include this statement: "This material is the result of work supported with resources and the use of facilities at the [name and location of VA medical facility]."

Acknowledge VA employment

Acknowledge employment of VA authors with VA title, name of VA medical facility, city, and state. Academic affiliate appointments can also be listed, but if research was funded only by VA, the VA affiliation should be listed first.

Include DVA/US Government disclaimer

"The contents do not represent the views of the U.S. Department of Veterans Affairs or the United States Government."

Link to <u>clinicaltrials.gov</u>

If your publication concerns a clinical trial or observational study that was registered on <u>clinicaltrials.gov</u>, include the NCT number in the publication. This allows the clinicaltrials.gov website to link your paper to the trial registration.

Deposit your manuscript in PubMed Central if the study was VA-funded

See guidance at: www.research.va.gov/resources/policies/public access.cfm

Notify ORD through PubTracker

Upon the paper's acceptance, notify ORD Communications through the VA <u>PubTracker</u>. This allows ORD to prepare media announcements, as appropriate, and to collect data regarding productivity of the VA Research program. Please note that this step also applies to meeting presentations.

Why work with the VA St. Louis Research Service?

St. Louis VA research has produced advancements in healthcare for Veterans:

Over 100 Affiliated Research Investigators

Approximately 170 active studies

Approximately \$4 million in Research expenditures annually

Research Strengths

Large cadre of accomplished researchers

Dual affiliation with Washington University & Saint Louis University

Responsive Executive and Administrative Team

Activated and engaged research committee chairs and members

Research is performed at:

John Cochran Division

Jefferson Barracks Division

Big Brother Big Sisters Building

Saint Louis University's Doisy Building (VA leased space)

Washington University's VA research investigators' labs (VA approved space)

Computer System

Our researchers have dedicated research servers that are employed for capture, assemblage, retrieval and analysis of all data related to research at the VASTLHCS. The research servers are located on the campus of the VASTLHCS. They meet all VA security requirements and are behind the VA firewall. Maintenance and analysis of our databases on these servers will markedly reduce security risks related to storage of protected health information or portable devices and enhance computer storage and data processing capabilities. Password protected access to the databases will be limited to approved personnel.

2023 VA St. Lous Health Care System Investigator of the Year Award

Dr. Sarah George, M.D.



VA Staff Physician, St. Louis VA Medical Center 2003-present

Professor of Internal Medicine, Division of Infectious Diseases, Allergy, and Immunology, Saint Louis University 2022-present

PI on more than 10 vaccine or treatment clinical trials including;

• A Phase I, Double-blind, Placebo-controlled Trial to Evaluate the Safety, Reactogenicity, and Immunogenicity of Yellow Fever Vaccine in 18-45 Year Old Healthy Adults, NIH/NIAID, June 2015-present.

• A Phase 1, Double-blinded, Placebo-Controlled Study of the Safety and

Immunogenicity of Alum Adjuvanted Zika Virus Purified Inactivated Vaccine in Flavivirus Naïve Adult Subjects, NIH/NIAID, March 2017-present.

- Determine if a Candidate Dengue Vaccine in Advanced Trials Induces Antigen-Specific Cellular Immunity That Mimics Immunity After Multiple Infections and Controls Antibody-Enhanced Viral Replication, VHA/ORD, July 2017-present.
- A Phase 3 Safety, Immunogenicity, and Lot-Consistency Trial of the VLP-Based Chikungunya Vaccine in Healthy Adults and Adolescents, Emergent Biosolutions, July 2021-December 2022.
- Durability and Mechanisms of Dengue Vaccine and Infection Mediated Immunity, VHA/ORD, projected start October 2023.

2023 VA St. Lous Health Care System Lifetime Achievement Award

Dr. Douglas Mann, M.D.



Ada L. Steininger Professor of Cardiology, Professor of Medicine, Cell Biology and Physiology, Washington University School of Medicine 2019 – present

• Leader in cardiac cellular and molecular physiology, innate immunity and inflammation and heart failure.

• Bibliography includes over 400 peer reviewed articles and editorials published, 1984 – present

• Funding has included collectively over 55 grants, federal and nonfederally funded, contracts for research and development and clinical trials.

Served as mentor for 46 research fellows from 1991 - present.

VA Funded Studies

<u>Ziyad Al-Aly, MD</u>

• Cause-specific mortality among users of proton pump inhibitor

Rachael Beard, MSN, M.Ed, EdD, RN

• Multisite replication of the transitional care model

Carlos Mizrachi-Bernal, MD

• Vitamin D and developmental origins of insulin resistance

Brian Dieckraefe, MD

- Circulating biomarkers for the detection of human liver diseases
- Novel Reg4-CD44 signaling pathway in colon cancer

Abinav Diwan, MD

- Targeting macrophage lysosome biogenesis program in cardiomyopathy and heart failure
- Mitophagy pathways in cellular cross-talk in the myocardium

Jill Elwing, MD

 CSP #577 – Colonoscopy vs fecal immunochemical test in reducing mortality from colorectal cancer (CONFIRM)

James Fleckenstein, MD

Molecular pathogenesis of enterotoxigenic Escherichia coli infections

<u>Sarah George, MD</u>

 Determine if a candidate dengue vaccine in advance trials induces antigen-specific cellular immunity that mimics immunity after multiple infections and controls antibody-enhanced viral replication

Leslie Gewin, MD

Epithelial Beta-catenin Signaling Improves Chronic Renal Injury

Amy Joseph, MD

- Storytelling to improve disease outcomes in gout: the STRIDE-GO study
- VA Rheumatoid Arthritis (VARA) Study

Peggy Kendall, MD

B Lymphocytes in autoimmune disease

<u>Jacki Kornbluth, PhD</u>

- Molecular Characterization of Anti-Tumor Activity Mediated by Extracellular Vesicles Derived from Natural Killer Cells
- NKLAM: An RBR E3 ubiquitin ligase essential for regulation of innate immunity

Daniel Kriesel, MD

• Leukocyte trafficking in thoracic grafts

Mauricio Lisker, MD

PREventing liver cancer Mortality through Imaging with Ultrasound vs. MRI (PREMIUM Study)

Andrea Loiselle, MD

Dissecting the Role of Dietary Protein on Monocyte/Macrophage mTOR

Spencer Melby, MD

• Contribution of inflammation and oxidative stress in pericardial fluid to postoperative atrial fibrillation after cardiac surgery

Jessi Hatfieldl, MD

 Project work as a determinant of health: a pragmatic trial of enhanced cognitive behavioral therapy to bolster competitive work and wellness in veterans with serious mental illness (WORKWELL)

Brian Muegge, MD

Enteroendocrine cell reprogramming during intestinal injury

Jason Napuli, MD

 CSP-2009 Sequential and Comparative Evaluation of Pain Treatment Effectiveness Response: The SCEPTER Trial

Jeanne Nerbonne. PhD

• Identification of novel cellular/molecular mechanisms and arrhythmia targets in heart failure

<u>Christine Pham, MD</u>

Immune-mediated pathways in pathogenesis of abdominal aortic aneurysm

Varun Puri, MD

Defining quality of care in lung cancer

Michael Rauchman, MD

Mechanisms and treatment of kidney fibrosis

• Million Veteran Program (MVP)

<u>Babak Razani, MD</u>

 Harnessing the autophagy-lysosomal biogenesis response in macrophages to treat atherosclerosis

Rajan Sah, MD

• Ion channel regulation of pancreatic islet cell function

Katherine Tam, MD

Prospective Survey for Healthcare Process Map

Robert White, MD

CIRB 22-65 Vet-PD: The Veterans Parkinson's Disease Genetics Initiative

Gregory Wu, MD

• Role of CSF microglia in health and disease

Mohamed Zayed, MD

CCR2 Targeted Molecular Imaging and Treatment of Abdominal Aortic Aneurysms

Non-VA Funded Studies

Rachael Beard, MSN, M.Ed, EdD, RN

• Multisite replication of the transitional care model

<u>Seth Eisen, MD, MSc</u>

Incidence of diabetes and infection in abatacept treated rheumatoid arthritis

Jesse Keller, MD

Novel risk prediction model for checkpoint inhibitor related autoimmune toxicities

Eric Knoche, MD

- Study evaluating the efficacy and safety of canakinumab versus placebo as adjuvant therapy in adult subjects with states AJCC/UICC v. 8 11-IIIA and 1118 (T>5cm N2) completely resected (RO) non-small cell lung cancer (NSCLC)
- A phase three, randomized, double blind, placebo-controlled study of Talazopari with Enzalutamide in castration-resistant prostate cancer
- A randomized, double-blind, placebo-controlled, multicenter phase III study of Olaparib plus Abiraterone relative to placebo plus Abiraterone as first-line therapy in men with metastatic castration-resistant prostate

<u>Geetha Maddukuri, MD</u>

• CSP 2008: Pentoxifylline in Diabetic Kidney Disease

Jay McDonald, MD

- CDC IRB and Implementation of the Expanded Access Program: "Expanded Access IND Protocol: Use of Tecovirimat (TPOXX[®]) for Treatment of Human Orthopoxvirus Infections
- VA trauma infectious diseases outcomes study

Ammar Nasir, MD

• Evaluation of treatment strategies for severe calcific coronary arteries: orbital atherectomy vs. conventional angioplasty technique prior to implantation of drug-eluting stents

Medhat Osman, MD

- A Multi-Center, Open-Label, Randomized Phase 1/2 Study of Copper Cu64PSMA I&T Injection in Patients with Histologically Proven Metastatic Prostate Cancer
- An International Prospective Open-label, Randomized, Phase III Study comparing 177Lu-PSMA-617 in combination with Standard of Care, versus Standard of Care alone, in adult male patients with Metastatic Hormone-Sensitive Prostate Cancer (mHSPC)
- Prospective comparison of pelvic CT or MRI plus 18F-NaF PET/CT to 18F Fluciclovine PET/CT in VA prostate cancer patients with BCR and a negative 99mTc-MDP bone scan
- VISION: an international, prospective, open-label, multicenter, randomized phase 3 study of 177LU-PSMA-617 in the treatment of patients with progressive PSMA-positive metastatic castration-resistant prostate cancer (MCRPC), of 177Lu-PSMA-617

<u>Jiafu Ou, MD</u>

- A randomized, double-blind, placebo-controlled multicenter trial, assessing the impact of inclisiran on major adverse cardiovascular events in participants with established cardiovascular disease (VICTORION-2PREVENT)
- Cardiovascular inflammation reduction trial
- Pragmatic evaluation of events and benefits of lipid-lowering in older adults

<u>Nathan Ravi, MD</u>

Preclinical development of reverse-engineered vitreous substitutes

Kavitha Reddy, MD

 Implementation of a pragmatic trial of whole health team vs. primary care group education to promote non-pharmacological strategies to improve pain, functioning and quality of life in veterans

Molly Sachdev, MD

• ARTESIA (Apixaban for the reduction of thrombo-embolism in patients with device-detected sub-clinical atrial fibrillation)

Martin Schoen, MD

• Antithrombotic therapy to ameliorate complications of COVID-19

Sarah Shia, MD

• Personalizing Cognitive Processing Therapy with a Case Formulation Approach to Intentionally Target Impairment in Psychosocial Functioning Associated with PTSD

Kaharu Sumino, MD

Intervention study in overweight patients with COPD

Theodore Thomas, MD

- A Phase II Study of Sotorasib (AMG 510) in Participants with Previously Treated Stage IV or Recurrent KRAS G12C Mutated Non-Squamous Non-Small Cell Lung Cancer (ECOG-ACRIN LUNG-MAP SUB-STUDY)
- LUNGMAP: A Master Protocol To Evaluate Biomarker-Driven Therapies And Immunotherapies In Previously-Treated Non-Small Cell Lung Cancer (Lung-MAP Screening Study)
- Phase 3 study of Pembrolizumab (MK-3475) in combination with concurrent Chemoradiation therapy followed by Pembrolizumab with or without Olaparib compared with concurrent Chemoradiation therapy followed by Duralumin in participants with unresectable, locally advanced, stage III Non-Small Cell Lung Cancer (NSCLC)

<u>Emad Zakhary, MD</u>

Carotid revascularization and medical management for asymptomatic carotid stenosis

Mohammed Zayed, MD

- Randomized, multicenter, controlled trial to compare best endovascular versus best surgical therapy in patients with critical limb ischemia
- Best-real world outcomes in critical limb ischemia registry
- PET-MR imaging of natriuretic receptor C (NPR-C) in carotid atherosclerosis
- R01 MRI perfusion study

VA St. Louis Research Affiliated Principal Investigator Publications, 2022

Long COVID after breakthrough SARS-CoV-2 infection. Al-Aly Z, Bowe B, Xie Y. Nat Med. 2022 Jul;28(7):1461-1467. doi: 10.1038/s41591-022-01840-0. Epub 2022 May 25. PMID: 35614233

Mental health in people with covid-19.

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Comparative Effectiveness of Sodium-Glucose Cotransporter 2 Inhibitors vs Sulfonylureas in Patients With Type 2 Diabetes-Reply.

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Racial Disparities in the Surgical Treatment of Clinical Stage I Non-Small Cell Lung Cancer Among Veterans.

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2023 VHA ORD Submissions Calendar

February 1st

BLR&D/CSR&D: Nominations for the Middleton Award and Barnwell Award

RR&D:

Pre-applications / Letters of Intent (LOIs)

Waiver requests for spring cycle

February 1st - March 8th

BLR&D / CSR&D Merit Review (MR) Parent award submission widow

February 15th - March 10th

RR&D MR Parent award submission widow

March 1st

HSR&D: Nominations for Promos

RR&D: Promos applications

April 15th

HSR&D: Career Development (CD) LOIs

May 1st

BLR&D/CSR&D:

LOIs for CD and Merit Review (MR) awards with LOI requirements

Off-Site Waiver Requests

Requests to exceed budget caps for Merit Review awards

RR&D: Pre-applications / LOIs and waiver requests for summer cycle

May 6th

HSR&D/QUERI: Intent to Submit deadline for summer cycle

May 11th

Waivers for exceeding budget caps

Waivers for offsite research

Waivers for IPAs in excess of 30% of personnel for Centers of Innovation (COINs) and 40% for non-COINs (Merit Review)

May 15th - June 8th

HSR&D MR Parent award submission widow

May 15th – June10th

RR&D MR Parent award submission widow

June 1st

BLR&D/CSR&D: Requests for eligibility and/or acceptance into the Non-Clinician Intramural Research Program

August 1st

RR&D:

Pre-applications / LOIs

Waiver requests for fall cycle

August 1st – September 7th

BLR&D / CSR&D MR Parent award submission widow

August 15th – September 10th

RR&D MR Parent award submission widow

September 1st

HSR&D: Nominations for RCS and Promos

September 1st

RR&D:

Promos applications

Paul B. Magnuson Award nominations

October 15th

HSR&D: CD LOIs

November 1st

BLR&D/CSR&D:

LOIs for CD and MR awards with LOI requirements

Off-Site Waiver Requests

Requests to exceed budget caps for Merit Review Awards

RR&D:

Pre-applications / LOIs

Waiver requests for winter cycle

November 3rd

HSR&D/QUERI: Intent to Submit deadline for winter cycle

November 9th

Waivers for exceeding budget caps

Waivers for Offsite Research

Waivers for IPAs in excess of 30% of personnel for COINs and 40% for non-COINs (Merit Review)

November 15th - December 8th

HSR&D MR Parent award submission widow

November 15th - December 10th

RR&D MR Parent award submission widow

December 1st

BLR&D/CSR&D: Requests for eligibility and/or acceptance into the Non-Clinician Intramural Research Program

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