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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.

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.

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
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 **Biomedical Laboratory Research & Development Service** (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 **Clinical Science Research and Development Service** (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 **Health Services Research and Development Service** (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 **Rehabilitation Research & Development Service** (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:**

<table>
<thead>
<tr>
<th>Merit Review Awards</th>
<th>Research Career Development Awards</th>
</tr>
</thead>
<tbody>
<tr>
<td>BLR&amp;D &amp; CSR&amp;D: $165K/yr, yr1-yr4</td>
<td>BLR&amp;D &amp; CSR&amp;D: PI salary support &amp; $105K/yr1 - $75K/yr, yr2 - yr5.</td>
</tr>
<tr>
<td>HSR&amp;D: $1.2M / maximum 4 yrs</td>
<td>HSR&amp;D: PI salary support &amp; $40K/yr, yr1 - yr3</td>
</tr>
<tr>
<td>RR&amp;D: $1.2M / maximum 4 yrs</td>
<td>RR&amp;D PI salary support &amp; $75K/yr, yr1 - yr5</td>
</tr>
</tbody>
</table>

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

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 (5/8ths) 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, 5/8ths 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 5/8ths VA paid appointment at the VAMC. This is conditional upon approval of the grant application for funding.

Alternatively, eligible PI’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 [www.facebook.com/VREFSTL](http://www.facebook.com/VREFSTL)
- Instagram @veteransresearch
- Twitter @VREFSTL
- Website [www.vrefstl.org](http://www.vrefstl.org)
- Or by contacting Allison Shafer, VREF Executive Officer at Allison.Shafer@va.gov

**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.Proside@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) Technology Transfer Program (TTP), 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 VA-developed 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.
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
(STL.IRB.Admin@va.gov)
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 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.

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

Subcommittee Administrator
Erin Torrence (Erin.Torrence@va.gov)
Chair: Dr. Marc Levin, M.D. (Marc-Levin2@va.gov)

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.

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 (Denise.Garnett@va.gov)
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.

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

Amy Garner, Rebecca Kammer, Emilee Nealy

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

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.

PREP Team
(STLPREP@va.gov)
Amy Garner
Rebecca Kammer
Emilee Nealy

IRB
IACUC
SRS
RDC
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, Explaining who we are and what we do, Connecting with them to know who they are, Actively listening to them, Responding to them with dignity and respect and Expressing gratitude for their service.

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 (Gary.Schofield@va.gov) 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
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

Notable Research: 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.

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 clinicaltrials.gov

If your publication concerns a clinical trial or observational study that was registered on clinicaltrials.gov, 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 PubTracker. 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. Louis 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. Louis 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 non-federally funded, contracts for research and development and clinical trials.
• Served as mentor for 46 research fellows from 1991 - present.
VA Funded Studies

Ziyad Al-Aly, MD
• 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

Sarah George, MD
• 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
Jacki Kornbluth, PhD
• 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 Hatfield, 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

Christine Pham, MD
• 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)

*Babak Razani, MD*

• 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

*Seth Eisen, MD, MSc*

• 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 AJCC/UICC v. 8 11-III A 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
Geetha Maddukuri, MD

- CSP 2008: Pentoxifylline in Diabetic Kidney Disease

Jay McDonald, MD

- 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

Jiafu Ou, MD

- 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

Nathan Ravi, MD

- 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
• ARTESTA (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)

**Emad Zakhary, MD**

• 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.
Mental health in people with covid-19.
Al-Aly Z.
PMID: 35172969

Comparative Effectiveness of Sodium-Glucose Cotransporter 2 Inhibitors vs Sulfonylureas in Patients With Type 2 Diabetes-Reply.
Al-Aly Z, Xie Y.
PMID: 34724023

Reg4 Interacts with CD44 to Regulate Proliferation and Stemness of Colorectal and Pancreatic Cancer Cells.
Bishnupuri KS, Sainathan SK, Ciorba MA, Houchen CW, Dieckgraefe BK.
PMID: 34753802

Acute and postacute sequelae associated with SARS-CoV-2 reinfection.
Bowe B, Xie Y, Al-Aly Z.
PMID: 36357676

The US Department of Veterans Affairs Science and Health Initiative to Combat Infectious and Emerging Life-Threatening Diseases (VA SHIELD): A Biorepository Addressing National Health Threats.
PMID: 36601554

Improved survival with post-diagnostic metformin and statin use in a racially diverse cohort of US Veterans with advanced prostate cancer.
Khan S, Chang SH, Hicks V, Wang M, Grubb RL 3rd, Drake BF.
PMID: 34811499

Emerging therapies in the management of Irritable Bowel Syndrome (IBS).
Elwing JE, Atassi H, Rogers BD, Sayuk GS.
Segmental Colitis Associated With Diverticulosis Masquerading as Polyploid-Appearing Mucosa in the Rectosigmoid Area on Endoscopy and as Focal Thickening on Imaging.
Nwankwo EC Jr, Khneizer G, Sayuk G, Elwing J, Havlioglu N, Presti M.
PMID: 35399418

Targeting the A3 adenosine receptor to prevent and reverse chemotherapy-induced neurotoxicities in mice.
PMID: 35093182

Blood-brain barrier penetration of non-replicating SARS-CoV-2 and S1 variants of concern induce neuroinflammation which is accentuated in a mouse model of Alzheimer’s disease.
PMID: 36682515

Enterotoxigenic Escherichia coli heat-labile toxin drives enteropathic changes in small intestinal epithelia.
PMID: 36371425

Tumor necrosis factor α impedes colonic thiamin pyrophosphate and free thiamin uptake: involvement of JNK/ERK1/2-mediated pathways.
Anthonymuthu S, Sabui S, Sheikh A, Fleckenstein JM, Said HM.
PMID: 36342158

Enterotoxigenic Escherichia coli Degrades the Host MUC2 Mucin Barrier To Facilitate Critical Pathogen-Enterocyte Interactions in Human Small Intestine.
PMID: 34807735
Quantifying Donor Deficits Following Nerve Transfer Surgery in Tetraplegia.

Blocking cell cycle progression through CDK4/6 protects against chronic kidney disease.

Midesophageal Metastatic Disease After Treatment of Gastroesophageal Junction Adenocarcinoma.

Characterization of uridine-cytidine kinase like-1 nucleoside kinase activity and its role in tumor growth.
Emily C Matchett 1, Elise C Ambrose 1, Jacki Kornbluth 1 2

Development and Validation of the VA Lung Cancer Mortality (VALCAN-M) Score for 90-day Mortality Following Surgical Treatment of Clinical Stage I Lung Cancer.

The Impact of Persistent Smoking After Surgery on Long-term Outcomes After Stage I Non-small Cell Lung Cancer Resection.

TRAF2, an Innate Immune Sensor, Reciprocally Regulates Mitophagy and Inflammation to Maintain Cardiac Myocyte Homeostasis.
**Finerenone in Patients With Chronic Kidney Disease and Type 2 Diabetes by Sodium-Glucose Cotransporter 2 Inhibitor Treatment: The FIDELITY Analysis.**
Diabetes Care. 2022 Dec 1;45(12):2991-2998. doi: 10.2337/dc22-0294. PMID: 35972218

**Mitigating COVID-19 Vaccine Waste Through a Multidisciplinary Inpatient Vaccination Initiative.**
Baumann N, Chen S, McDonald JR, Davis MH, Petroff C, McKelvy P.

**Universal masking to control healthcare-associated transmission of severe acute respiratory coronavirus virus 2 (SARS-CoV-2).**
Thompson ER, Williams FS, Giacin PA, Drummond S, Brown E, Nalick M, Wang Q, McDonald JR, Carlson AL.

**Stepwise Multimodality Imaging Assists in Atrial Myxoma Diagnosis and Management.**
Wong KE, Mani K, Melby SJ, Hou P, Ou J.

**Islet primary cilia motility controls insulin secretion.**
Cho JH, Li ZA, Zhu L, Muegge BD, Roseman HF, Lee EY, Utterback T, Woodhams LG, Bayly PV, Hughes JW.

**Safety Profile of Rapamycin Perfluorocarbon Nanoparticles for Preventing Cisplatin-Induced Kidney Injury.**

**Influences of polycyclic aromatic hydrocarbon on the epigenome toxicity and its applicability in human health risk assessment.**
Durgesh Nandini Das, Nathan Ravi

**TFEB signaling attenuates NLRP3-driven inflammatory responses in severe asthma.**
Neutrophil DREAM promotes neutrophil recruitment in vascular inflammation.
PMID: 34751735

Autophagy in Atherosclerosis: Not All Foam Cells Are Created Equal.
Francis GA, Razani B.
PMID: 35298303

Unanswered questions in cancer-associated thrombosis.
Sanfilippo KM, Moik F, Candeloro M, Ay C, Di Nisio M, Lee AYY.
PMID: 35611985

Thrombosis and bleeding in hematological malignancy.
Wang TF, Leader A, Sanfilippo KM.
PMID: 36030068

Evaluation of the Khorana score for prediction of venous thromboembolism in patients with multiple myeloma.
PMID: 35028491

Venous thromboembolism and risk stratification in hematological malignancies.
Sanfilippo KM.
PMID: 36210555

Standardization of risk prediction model reporting in cancer-associated thrombosis: Communication from the ISTH SSC subcommittee on hemostasis and malignancy.
PMID: 35635332
Survival of veterans treated with enzalutamide and abiraterone for metastatic castrate resistant prostate cancer based on comorbid diseases.
PMID: 3610450

Different risks of hemorrhage in patients with elevated international normalized ratio from chronic liver disease versus warfarin therapy, a population-based retrospective cohort study.
Afzal A, Gage BF, Suhong L, Schoen MW, Korenblat K, Sanfilippo KM.
PMID: 35491428

Effect of Androgen Suppression on Clinical Outcomes in Hospitalized Men With COVID-19: The HITCH Randomized Clinical Trial.
PMID: 35438754

Racial Disparities in the Surgical Treatment of Clinical Stage I Non-Small Cell Lung Cancer Among Veterans.
PMID: 35405111

Treating advanced lung cancer in older veterans with comorbid conditions and frailty.
PMID: 35853764

Risks and burdens of incident diabetes in long COVID: a cohort study.
Xie Y, Al-Aly Z.
PMID: 35325624

Xie Y, Xu E, Bowe B, Al-Aly Z.
Risks of mental health outcomes in people with covid-19: cohort study.
Xie Y, Xu E, Al-Aly Z.
BMJ. 2022 Feb 16;376:e068993. doi: 10.1136/bmj-2021-068993.
PMID: 35172971

Impact of Socioeconomic Status on Major Amputation in Patients with Peripheral Vascular Disease and Diabetes Mellitus.
Fan RR, Gibson AK, Smeds MR, Zakhary E.
PMID: 35398196
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 – June 10th**

**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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