



Clinical Science Research and Development



Terri Talks

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Message from the Director

Hello again! We in CSRD have started processing new Spring 2021 applications and lining up our review panels – it is always an exciting time to see what innovative ideas are being presented. As you all must know, we continue to follow the delays and interruptions in research from COVID, and we want to work with you to problem solve. Similarly, we are counting on everyone to make sure budget resources are being used as planned, or per our notes below, please work with us on reprogramming. We wish you the very best in your important work as we hopefully turn towards a healthy, new Spring, Terri

Career Development Awardees

Congratulations and welcome to CSRD's recently funded Career Development awardees! Our CDA program is intended to attract, develop, and retain talented researchers working in areas of particular importance to improve the health and care of our nation's Veterans. CSRD has a rich history of supporting investigators during their early research careers who have gone on to serve as long-standing, independently funded scientists, Center Directors, and research administrators, e.g., Associate Chiefs of Staff for Research, etc. Our newest awardees are:

Ryan Michael Broxterman, Ph.D., Salt Lake City VA

“Mechanisms of systemic dysfunction responsible for exercise intolerance induced by breasts cancer, cytotoxic chemotherapy, and endocrine therapy in Veterans”

Primary Mentor: Russell Richardson, Ph.D. Formal Mentors: Markus Amann, Ph.D.; Norah Henry, Ph.D., M.D.; Sarah Colonna, M.D.; Haaland Benjamin, Ph.D.

Noam Jacob, M.D., Ph.D., Los Angeles VA

"Microbiomal Mediators of TL1A-induced-Fibrosis"

Mentor: Joseph Pisegna, M.D.

Co-mentor: Stephan Targan, M.D.

Matthew Klein, M.D., Ph.D., Bronx VA

"Identifying neurobiological vulnerabilities in reward processing associated with suicidal behavior in Primary Mentor: Erin Hazlett, Ph.D."

Co-mentors: Marianne Goodman, M.D.; James Murrough, M.D., Ph.D.

Crystal Lantrip, Ph.D. Temple VA

"Repetitive Transcranial Magnetic Stimulation Augmented Written Exposure Therapy for Veterans with PTSD"

Mentors: Suzannah Creech, Ph.D.; Paul Holtzheimer III, M.D.

Co-mentors: Sara Dolan, Ph.D., Steven Nelson, Ph.D.

Chen Lin, M.D., Birmingham VA

"A randomized placebo-controlled trial of methylphenidate in Veterans with a diagnosis of post traumatic stress disorder and recent cerebral stroke"

Primary Mentor: Peter King, M.D.

Mentors: Charity Morgan, Ph.D.; Lori Davis, M.D.; Jerzy Szarfarski, M.D., Ph.D.

Dragana Lovre, M.D., New Orleans VA

"Effects of Novel Estrogens on Glucose and Lipids in Postmenopausal Prediabetic Women Veterans"

Primary Mentor: Frank Mauvais-Jarvis, M.D., Ph.D.

Co-Mentors: Vivian Fonseca, M.D.; Edwin Swiatlo, Ph.D., M.D.

Shilpa Sharma, M.D., Los Angeles VA

"Dynamic Changes in Erythrocyte 2,3 DPG as a Driver of Cardiac Dysfunction in End Stage Kidney Disease,"

Primary Mentor: Kim-Lien Nguyen, M.D.

Co-mentors: Tomas Ganz, Ph.D., M.D., Isidro Saluki, M.D.; Joachim Ix, M.D.

Jonathan R. Young, M.D., Durham VA

"Neuroimaging correlates and feasibility of transcranial magnetic stimulation (TMS) to improve smoking cessation outcomes in Veterans with comorbid PTSD"

Primary Mentors: Jean Beckham, Ph.D.

Co-mentors: Lawrence Appelbaum, Ph.D.; Eric Dedert, Ph.D.; Scott Moore, M.D.

Amin Zand Vakili, M.D., Ph.D., Providence VA

“Developing Computational Nosologies of Posttraumatic Stress (PTSD)”

Primary VA Mentor: Noah Phillip, M.D.

Secondary VA Mentors: Benjamin Greenberg, Ph.D., M.D.; M. Tracie Shea, Ph.D.; Jerome Sanes, Ph.D.

Secondary Mentors (Brown University): Michael Frank, Ph.D., Christopher Schmid, Ph.D.

Projects with Delayed Start in JIT

CSRD is closely examining projects that have delayed their start in our JIT system. This is a key tool in our managing efficient budget execution and start up. Projects with delays past the 180 days risk having funding notices rescinded. Two specific requests for the field are:

- We need for multisite commitment for ALL sites to complete on time. Our records show that often the primary site is in fact on schedule, but LSI applications or other non-primary site issues cause unneeded delays. We'll be working on developing a communication plan around this requirement for multisite applications, and ask the PIs of multisite studies to be working closely with local site research offices to address JIT requirements for their stations.
- Extension requests for those projects that are not able to make the requirement to clear JIT in 180 days must include a **detailed timeline** of attempts to obtain regulatory approval and anticipated date(s) for submission of remaining JIT documents. Requests without this information will be returned to the research office.

Two Notes Regarding FY21 CSRD Budget:

1. Requests for Redistribution of Funds

Requests for CSRD to pull back project funds for this fiscal year for redistribution in later year are welcome but need to come in as soon as possible. Our goal is to receive all requests by March 31, in the form of a PMO. Based on the needs of the PI, we will either extend the end date of the project or send funds back to PI in a different FY (before last). PIs should discuss the redistribution opportunity with their Research Service AOs and budget staff, who recently received training on redistributions.

2. Potential FY 21 Supplements

Because of the movement in fund redistribution and close eyes on execution of dollars for this fiscal year, CSRD **may be** issuing a request for supplemental funds that could be fully executed this year. This note is for investigators to be prepared for this **potential** opportunity.

Inclusion of Non-Veterans

In recent months we have seen PIs request non-Veteran enrollment waivers due to running behind on meeting recruitment targets for CSRD projects. We encourage PIs to think of other ways to boost recruitment – other than enrolling non-Veterans – as first next steps. We will remind PIs that financial responsibility for adverse events which may occur in non-Veterans is borne by CSRD. CSRD has updated the form for non-Veteran waiver. Please use the current version on the CSRD website. The change requires more detailed justification than previously, including risk-assessment by PI in the case of studies that are greater than minimal risk. LINK: [Non-Veteran Waiver form \(va.gov\)](https://www.va.gov/csrd/non-veteran-waiver-form/)

LOI Guidance for Collaborative Merit

For the BLRD/CSRD Collaborative Merit RFA, as part of the letter of intent submission, if one of the proposed projects is a clinical trial, in addition to the LOI tied to this RFA, a separate LOI must be submitted for the trial project (following our clinical trial LOI template), and can be submitted as a package following the collaborative LOI submission guidance.

MVP Data Access Update.

The first possibility for all VA investigators to submit research proposals for studies requiring access to MVP data will open in the Fall 2021. More information and documents needed for submission of Letters of Intent can be found at GenHub: <https://vaww.genisis.med.va.gov/genhub/file/group/1/all/486> . Please note that access requires registration on the GenHub the main page: <https://vaww.genisis.med.va.gov/genhub/>

All of Us Research Program

The All of Us Research Program (AoURP) is a large collaborative research cohort program sponsored by the National Institutes of Health (NIH) that aims to enroll a diverse group of one million or more participants who provide survey data, biospecimens, physical measurements, and access to their electronic health records. The VA is participating in the AoURP as healthcare provider organization, and has been enrolling Veterans in AoURP since 2018. The AoURP currently has ten active VA Medical Center sites participating in recruitment and enrollment of Veterans across the country with plans to add additional sites

this year. The enrollment activity is coordinated centrally under the direction of Co-Principal Investigators Philip Tsao, PhD., Sherry Sawyer, Ph.D. and Jason Vassy, M.D.

The AoURP has created a digital data resource for researchers that enables researchers to view data, create custom cohorts and pull and manipulate data sets, known as the Researcher Workbench. We are excited to share with you that the VA has recently entered into a Master Data Use Agreement with the AoURP that allows VA researchers to use the AoURP Researcher Workbench. For information on available data and the process for accessing data, please visit www.researchallofus.org. Any VA employee approved to conduct research and who has an eRA Commons account can register and request access to the data through a personalized workspace. VA Investigators are reminded to follow VA Directives and local policy regarding the need for R&DC approval on work proposed. ORD will be receiving monthly reports of registered VA users and will share that information with the appropriate research office.

If you have questions about the AoU research program, please email Sherry Sawyer, PhD (Sherilyn.Sawyer@va.gov).



CSR Staff Highlight: Lisa Eiben

Lisa Eiben is CSR's one and only Administrative Officer and supports CSR, ORD, and the clinical science field at large. She wears many hats in covering areas for internal customers to include budget execution and management, HR processing, acquisitions review and approval, contract review and contract project management, research support, and executive planning. For customers on the external side, she assists in budget execution and management, research support, and providing timely responses/problem resolution to the myriad of inquiries that come in. Lisa started with VA in September 2019, coming from a 22-year run at NIH, and quickly transitioned to remote working with the entire ORD office in March 2020 due to COVID. She is originally from Cleveland, Ohio but has called Baltimore, Maryland home for the last 37 years.

Research Supplements to Support Diversity due June 1

Eligible PIs with VA Merits with at least 2 years remaining may apply for this supplement. For information or to receive a copy of the announcement, email Carol.Fowler@va.gov.

Please Meet and Greet Us

Until we are able to travel, CSR staff members will be attending virtual meetings. One such opportunity is listed below:

- 2021 Virtual Society of Biological Psychiatry (SOBP) Annual meeting April 29-May 1.

CSRD Contact Information

General Mailbox: VHABLRD-CSRD@va.gov

Just in Time: <https://vaww.gateway.research.va.gov/jit/Default.asp?>

Career Development: VHACADEReview@va.gov

Clinical Trials: clin-review@va.gov

DEAN Annual Report

CSRD sits organizationally within the VA's Office of Research & Development (ORD), and as we work up the chain, ORD reports up through the Office of Discovery, Education & Affiliate Networks (DEAN). Below is the DEAN office Annual Report for 2020 which highlights some neat contributions - [DEAN Annual Report 2020.pdf \(va.gov\)](#)

Sent to Email Address on behalf of US Department of Veterans Affairs

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