

**From:** VHA BLRD-CSR  
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## Clinical Science Research and Development



# Terri Talks

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## Message from the Director: Inclusion is Key

I hope that the message of inclusivity and diversity of representation is foremost in CSR investigators' minds as they develop recruitment and enrollment plans for research volunteers in study plans. While we continue to struggle within our population to recruit overall, there are resources that can be brought to bear for targeted outreach. I would encourage you to conduct realistic assessments of subject demographics before submitting applications to be considered for funding. If you anticipate issues (and you should!), we will welcome your questions and provide advice regarding what resources you might also consider in order to have a true representative study population. This consideration is key to presenting inclusive and generalizable findings. Please let us know how we can help ensure the best representation in our clinical studies, *Terri*

## First Diversity Supplement Awarded

CSRSD is pleased to welcome our first Awardee for the Office of Research and Development (ORD) Research Supplements to Promote Diversity, Nadir Balba, Ph.D., from the Portland, OR VA Medical Center. These competitive awards are intended to provide supplemental funds to a VA Merit PI in order to offer a mentored research experience to an early career scientist from an underrepresented background. The goal is that the awardees work to prepare a VA Career Development Award application. Dr. Balba will be working with his funded VA mentor, Dr. Miranda Lim, (PI of: CX-002022-02, "Supplementation with Amino Acid Rehabilitative Therapy in TBI (SmART-TBI): A Randomized Placebo-Controlled Trial to Improve Sleep"), to pilot an internet-delivered mindfulness intervention for Veterans with TBI/PTSD. Many congratulations to Drs. Balba and Lim as they pursue this highly significant research for our Veterans together.

## Spring 2021 Round of Review Ends

We have just finalized funding decisions from the **Spring 2021 round of review**. We want to congratulate the entire group of investigators who submitted very competitive applications. We thank all of our scientific peer reviewers (VA and non-VA) for their critical contribution to this process. And we are grateful to all of our Scientific Portfolio Managers for the hours they put into making sure the slate of to-be-funded applications was in good shape. While the Intent to Fund notices will proceed, we should note that the one thing that everyone will quickly pay attention to is the associated list of requirements for each funded program as specified in our **Just in Time (JIT) system**. This is the very first step in successfully launching studies and effective budget management – resolving JIT elements and starting projects as quickly as possible. Thank you in advance to PIs and research offices for working on JIT as soon as possible.

## Fall 2020 Documents due in JIT

Many projects approved in Fall 2020 are approaching the 180-day deadline to satisfy all requirements in Just-In-Time (JIT) to be cleared for funding. CSRSD is requesting that research offices provide the necessary documents by the upcoming deadline (180 days) as soon as possible. This is critical for our budget execution plans.

## Reminder to Report COVID-19 Delays

CSRSD is reminding investigators when they submit their annual required progress reports (RPPRs), they should be cataloguing delays that have occurred in their research related to COVID-19 impacts. This then helps serve as both information to us as well as a record of what has impacted each of you.

## JAMA Special Communication Announced

Special Communication focusing on the research of Dr. Murray Stein, San Diego VA, and Dr. Christopher O'Donnell, Boston VA, was published July 14 in *JAMA Cardiology*. This emanated from a National Heart Lung and Blood Institute workshop on "The Cardiovascular Consequences of Post-Traumatic Stress Disorder" they co-chaired in 2018 that saw heavy

VA clinician researcher and ORD representation including Drs. Mario Rinaudo, Vetisha McClair, and Terri Gleason.

The article, "Posttraumatic Stress Disorder and Cardiovascular Disease: State of the Science, Knowledge Gaps and Research Opportunities," and accompanying podcast can be found at this link:

<https://jamanetwork.com/journals/jamacardiology/article-abstract/2781972>

## Diabetes Article Highlighted

Dr. Elias Spanakis of the Baltimore VA and his colleagues have published results of his CSRD-funded clinical trial on reducing abnormal glucose control in inpatient setting in a prestigious diabetes journal, *Diabetes Care*. Abnormal glucose control in inpatient setting is associated with adverse clinical outcomes. Efforts to control the glucose levels in high-risk patients with type 2 diabetes can predispose them to hypoglycemia and associated morbidity. Dr. Spanakis evaluated the effects of glucose telemetry system (GTS) that wirelessly transmits the real-time continuous glucose monitoring (RT-CGM) values to a centralized monitoring system at the nursing station on the patient care. The results from this clinical trial suggests that RT-CGM/GTS can decrease the hypoglycemia in these patients, thus improving their care. See the article at:

<https://doi.org/10.2337/dc20-0840>



## CSRD Staff Highlight: Welcome, Nick Simon!

On July 19, Dr. Nicholas (Nick) Simon joined CSRD as a Health Science Specialist and Scientific Portfolio Manager in Oncology. Nick is coming from the DoD where he was a Science Officer and Grants Officer Representative for the Breast Cancer Research Program, Congressionally Directed Medical Research Programs (CDMRP), U.S. Army Medical Research and Development Command. At CDMRP he managed a wide variety of basic, translational, and clinical research grants, served as chair for CDMRP's Science Officer Training Program, and participated in an initiative to analyze the success rate and risk factors of CDMRP-funded clinical trials. Prior to that he was a research fellow at the Johns Hopkins Sidney Kimmel Comprehensive Cancer Center, where he characterized novel relationships between DNA repair proteins and radiation resistance in glioblastoma multiforme cancers.

He earned his B.S. in Biochemistry and Molecular Biology from Michigan State University and his Ph.D. from the University of Pittsburgh's Molecular, Cell, and Development Biology program, where his doctoral thesis focused on characterizing novel inhibitors of the main helicase in DNA replication. Nick enjoys being outdoors and is an avid hiker.

## CSRD Bids Farewell to Dr. Cody

CSRSD bids a very fond farewell to Dr. Marisue Cody who has been ORD Director of Operations. In this role, Marisue has guided both the field and CSRSD to success on many, many administrative fronts and through challenges as well. We wish her the very best in retirement.

## CDA Symposium set for September

Our annual Career Development Symposium for awardees is being organized. We will plan to convene virtually again this year with the first and third year awardees across BL and CS. Monday, September 13, and Tuesday, September 14 for the bulk of the meeting, with Thursday, September 16, as the day for SPMs to meet with awardees in their portfolios. This is the same format as the 2020 meeting. This will help facilitate their awardees' participation in any way they can. Points of Contact: [Eric.schwinder@va.gov](mailto:Eric.schwinder@va.gov) and [Mark.Roltsch@va.gov](mailto:Mark.Roltsch@va.gov)

## DMC Seeking Members

CSRSD's Centralized Data Monitoring Committee (DMC) is currently seeking members for two panels – Medical/Surgical (M/S) and Psychiatric, Behavioral Health and Neurologic Disorders (PBN). The DMC is an independent multidisciplinary group that provides ongoing oversight and monitoring of funded studies focusing on safety and feasibility, participant accrual and retention, adverse events monitoring, and data analyses. Qualifications for membership include funding history and clinical trial experience, academic position of associate professor or above, a solid publications record, and review experience. Members are needed from the following areas: cardiology, pulmonology, oncology, urology, neurology, internal medicine, physical medicine and rehabilitation, and biostatistics. For more information, please contact Dr. Tamara Paine ([Tamara.Paine@va.gov](mailto:Tamara.Paine@va.gov)).

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