



Clinical Science Research and Development



Terri Talks

Vol. 3, No. 10, 2021.10.27

Message from the Director

In this newsletter, I'd like to talk about feasibility. Researchers in CSRD will most likely quickly think of issues related to participant enrollment and recruitment as a high risk to clinical research feasibility. However, I want to mention that there are many other potential risks to studies that we uncover in the process from initial evaluation by peer review experts to actual start up and implementation. It is truly unfortunate when a planned agreement or product availability changes along the project lifespan. Agreements span the range from use of affiliate university space or equipment to anticipated provision of materials from commercial partners. I send this note to encourage investigators to foster and strengthen their Letters of Intent, applications and funded work by paying attention to all of the components needed to complete a study as early and often in the process as possible. Conversations about cooperation and agreements can go "stale" between the time of application to actual study approval and start up. Several late-breaking examples we have encountered recently have included manufacturing schedules and pharmaceutical agents preventing start up – these cause us to seriously consider withholding or even withdrawing funding for the work. We continue to encourage good communication with our office just as soon as these issues are identified, as we can point to success stories when we have all worked together to find alternative solutions.

Best wishes, Terri

Letter of Intent Deadline is November 1

For investigators interested in submitting an application for the Spring 2022 review round that requires a letter of intent (LOI), the deadline is November 1, 2021. These include LOIs for clinical trials, career development awards, and multiple BLRD opportunities. Please read

instructions closely and submit via the appropriate mechanisms. Guidance is located here: https://www.research.va.gov/services/shared_docs/resources.cfm#4.

Funding Opportunity Announced: Post-COVID-19 Conditions

A new Program Announcement at [Clinical Science Research and Development \(va.gov\)](https://www.research.va.gov) provides a cross-Service announcement regarding an upcoming opportunity for research funding on post-COVID-19 conditions. This announcement provides an initial overview of the program to help interested investigators to begin collaborative and preparatory discussions in advance of an expected November RFA. More information will be forthcoming.

MVP Data to be Available

Million Veteran Program (MVP) data will be available for ALL ELIGIBLE VA investigators for Merit projects beginning the Spring 2022 cycle for Biomedical Laboratory Research and Development (BLRD) and Clinical Science Research and Development Service (CSRD) and the Summer 2022 cycle for the Health Services Research and Development (HSR&), and Rehabilitation Research and Development (RRD). Please follow submission requirements for your particular Service and RFA.

You can find information about the available MVP data here:
<https://vaww.genisis.med.va.gov/genhub/>

Job Opportunity Open Until November 2

Health Science Officer (Exposure Portfolio Manager, BLR&D, GS-0601-14)

Washington, DC

Announcement Open Period: Wednesday, October 20th, 2021 to Tuesday, November 2nd, 2021

You may select the link below to quickly navigate to the announcement

<https://www.usajobs.gov/GetJob/ViewDetails/617849600>

Need Continues for DMC Members

CSRD'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).

CSRD Staff Highlight:

Happy Fall from Historic Harpers Ferry

Biking, hiking, walking, and picnicking were on the “agenda” as available CSRD staff members and spouses converged on historic and beautiful Harpers Ferry in West Virginia on Saturday, October 23. This marked the first in-person “meeting” for CSRD since maximum telework began in March of 2020 due to the COVID-19 pandemic.



From left: Patrick O'Shea, Miriam Smyth, Nick Simon, Lisa Eiben, Kristina Nord, Terri Gleason, Jana Drgonova, Tomas Drgon, Steve Gleason, and Lucindia Shouse.

– Photo by Bobby Shouse



From left: Lisa, Kristina, and Lucindia

--Photos by Bobby and Pat

From left: Miriam, Lisa, Tomas, Lucindia, Kristina, Nick, and Terri

In front: Jana



CSRD Contact Information

General Mailbox: VHABLRD-CSRD@va.gov

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

Career Development: VHACADEReview@va.gov

Clinical Trials: clin-review@va.gov

Newsletter: Lucindia.Shouse@va.gov

