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Clinical Science Research and Development

VA



U.S. Department of Veterans Affairs
Veterans Health Administration
Office of Research & Development

Terri Talks

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Message from the Director

Again, we hope this newsletter finds each of you safe and healthy. It is the time of the year where we are anxiously looking forward to both holidays personally as well as the end of our review cycle where new projects are identified for funding. Of particular importance to us is the pace of activity across our application lifecycle and whether that is impacted by the pandemic. Our application lifecycle starts with the intake of new ideas in the form of letters of intent all the way through to funding decisions to start new projects and following through to successful completion and sharing results. We just finished the review of the first stage of the cycle – letters of intent – for clinical trials and career development. It is gratifying to see a lot of good ideas proposed for trials, but we did note a small decrement in the number of career development applicants to note. Considering we also recently expanded the program to include special emphasis CDA1 awards, this is an early concern which we hope will turn around for the next cycle with increased numbers of applicants. Please reach out AND conduct outreach to highly qualified young investigators to let them know about this important VA mentoring training research program and all the opportunities it provides. Please also review the trial opportunities related to COVID19 described below. Most importantly, CSRD wishes you and yours a very Happy Thanksgiving break,

Terri Gleason, Director, CSRD Service

Update: VA CURES Program of Clinical Trials for COVID-19

Webpage for VA CURES Program

The VA CURES Program has launched a webpage describing activities and trials for COVID-19. See: https://www.research.va.gov/services/csrd/va_cures/

LOI Solicitation for VA Cures Program Trials

CSR&D is soliciting Letters of Intent for clinical trial students that could be aligned under VA CURES, a program of master protocols for **COVID-19**. The first deadline is **December 14, 2020**. Details are also on the VA CURES Program webpage: https://www.research.va.gov/services/csrd/va_cures/.

VA CURES-1 Trial

The VA CURES-1 trial of convalescent plasma is starting to enroll, with the Houston VA Medical Center the first of many sites to begin on November 16. R&D Committee approval is required for any site following VA Central IRB review and approval. Thank you in advance for your support locally to ensure this important study is reviewed as efficiently as possible even if an ad hoc R&DC meeting is needed.

Other VA CURES Links:

- **CSR&D Home Page** (<https://www.research.va.gov/services/csrd/>): See the bullet list of links as well as the announcements section in the upper-right corner
- **VA Research on COVID-19 Page** (<https://www.research.va.gov/covid-19.cfm>): See the section on VA CURES under Active Research

Administrative Hold Reminder

Please be reminded to send information to CSR&D on any study that had been on hold when that status changes. We still need the field to provide updates of studies that have come off the holds (local or national). Please email CSR&D: clin-review@va.gov when project status changes (onto a new hold or removing a standing hold). CSR&D studies on hold are moving well below 100 in number, and we hope facilities continue to update us as hold changes occur.

SPRINT Planning Award RFA Announced

The VA Health Services Research and Development (HSRD) Suicide Prevention Research Impact NeTwork (SPRINT) intends to award approximately \$100,000 in funding for planning awards in funding for planning awards in FY2021 for investigators conducting or wishing to conduct suicide prevention research. The RFA that provides more information may be accessed at <https://www.hsrdr.research.va.gov/centers/core/SPRINT-RFA.pdf>. Letters of Intent are due by close of business on **December 18, 2020**. Questions may be sent to Molly Kessner at SuicidePreventionResearch@va.gov.

VA Phenomics Library Initiative

The VA Phenomics Library (VAPheLib) is an ORD-sponsored initiative for creating a centralized, VA-wide, community resource for storing, archiving and sharing phenotype definitions, data mapping and other metadata used in VA projects and publications. Phenotyping is the process often used to identify patients for a condition using data elements of the Electronic Medical Records, such as structured (ICD and CPT codes, electronic prescriptions, vital signs) and unstructured (clinical notes) data. The VAPheLib will improve reusability and scalability of information across VA projects, enhance collaboration, and serve as a resource for identifying eligible cases for VA research such as clinical trials or epidemiological studies. Researchers will benefit by having access to already developed phenotypes, identify potential collaborators, and collectively advance phenomics science in VA research community.

Applicants proposing to develop and validate new phenotypes as part of their VA funded research, including the recently funded COVID-supplements, should plan to contribute their phenotyping algorithm, codes, and validation processes to the VAPheLib. Please see below to learn more.

- **Become a User!**

- Browse VAPheLib:
https://vhacdwdwhweb100.vha.med.va.gov/phenotype/index.php/VA_Phenomics_Library
- Learn more about VAPheLib through an archived cyberseminar:
https://www.hsrdr.research.va.gov/for_researchers/cyber_seminars/archives/video_archive.cfm?SessionID=3814
- Please also join the [VAPheLib ListServ](#) by clicking on the link, or send an email to VAPHELIB-L@VAWWW.LISTSERV.VA.GOV to receive frequent updates and be part of ongoing discussions.

- **Become a Contributor! Become a Partner!**

- Join the partners group by contributing and sharing your expertise with VA community
- You can learn more about how to become a contributor:
https://vhacdwdwhweb100.vha.med.va.gov/phenotype/index.php/How_to_contribute

- **Feedback – We want to hear from you!**
 - Contact VAPheLib@va.gov :
 - For more information on the VA Phenomics Library
 - For suggestions, questions, and comments

CSRD Investigators Encouraged to Apply for HSRD COVID-19 Collaboratory

Request for Concept Paper Proposals: COVID-19 Observational Research Collaboratory (CORG)

Health Sciences Research and Development has announced an opportunity for investigators to compete for funds to lead the COVID-19 Observational Research Collaboratory (CORG). CORC will report to an interagency Executive Committee, which will include representatives from VA (ORD, HSRD, CSRD, CSP, PMB, ESP) and FDA.

Interested teams should submit concept papers in the following format:

- Description of how CORC will be organized, with leads for each activity (long-term outcomes study, Data/Methods Core, Administrative Core) clearly indicated (~2 pages).
- Description of long-term outcomes research questions of interest, including those explicitly mentioned above (~ 2 pages).
- List of key personnel, including brief descriptions of relevant expertise (~2 pages).

Timeline

Concept papers should be submitted by email to Alexandra Neuhaus-Follini at Alexandra.NeuhausFollini@va.gov by **December 2, 2020**. Proposals will be reviewed in early December and the most qualified team(s) will be invited to submit full proposals with relatively quick turnaround early in 2021. If multiple teams submit excellent and complementary concept papers, HSR&D may ask teams to consider merging prior to the submission of full proposals.

Please see attachment for more details.

Retirement Congratulations!

Reda Domenic, Ph.D., retired November 21 after a 40-year career with the VA including serving

as Director of the VA Cooperative Studies Program Coordinating Center (CSPCC) in Hines, IL, since 2007 and providing leadership for CSRD's Centralized Data Monitoring Committee since 2008. His contributions have been noteworthy for the success of the DMC as well as the entire program over the past 12 years. He has served as a trusted and expert advisor in the conduct of our important efforts to advance evidence-based treatments for Veterans in all of his work. In addition to managing the DMC, his support has included clinical trials advice and consultation, leading planning efforts, serving as statistical reviewer, and a CSRD training program for trialists. We will miss him but are encouraged that he will maintain a Without Compensation (WOC) appointment at Hines.

Thank you, Dr. Reda, for all your contributions. We wish you the very best upon your accomplishments and service!

Barnwell applications due February 1

The John B. Barnwell Award is CSRD's highest honor for outstanding achievement in clinical science research. Nomination packages are due by close of business on February 1, 2021.

The Barnwell Award is given for outstanding scientific achievements in clinical research that advance the diagnosis, prevention and/or treatment of diseases and disorders in the Veteran population.

Nominations may come from the VA Medical Center or CSRD can invite researchers to submit an application. **All applicants must apply through their local R&D Office.** To be eligible for the Barnwell Award, nominees must meet specific qualifications. Please review the program guide and instructions posted on the website for further details or contact Dr. Mark Roltsch, mark.roltsch@va.gov, if you have questions.

The information may be found on the ORD website by searching Barnwell Award at:

https://www.research.va.gov/services/csrd/research-awards.cfm?_ga=2.56572011.1990953416.1542631466-377307463.1536175624#barnwell

Please Meet and Greet Us

Until we are able to travel, CSRD staff members will be attending virtual meetings:

- American College of Neuropsychopharmacology Annual Meeting December 8 (NIH Institute Director's session including focus on VA's diversity and inclusion efforts with Q&A and an update on VA COVID activity with Q&A, followed by a networking session for additional questions). Dr. Gleason will be presenting on VA funding opportunities as well.
- (ADACE) Alcohol & Drug Abuse Center of Excellence Scientific Virtual Retreat, December 15

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

CSP Job Opportunities Shared

The VA Cooperative Studies Program (CSP), a clinical trial investigation program, is anticipating two new recruitment efforts – **Chief of Biostatistics** and **Associate Center Director for Technical Operations** – for one of its Clinical Trials Coordinating Centers. These positions will be located at the VA Medical Center in Hines, Illinois (in the Chicagoland area).

USAJOBS.gov announcements are expected to be released in the coming weeks. For inquiries about these positions or the Hines CSP Coordinating Center, please contact:

Joyce Gilroy

Associate Director for Administrative Operations,
Cooperative Studies Program Coordinating Center

Hines VA Hospital, CSPCC (151K)

5000 South 5th Avenue, Building 1, Room B-237

Hines, Illinois 60141-3030

e-mail: Joyce.Gilroy@va.gov phone: 708-202-5850 fax: 708-202