



Clinical Science Research and Development



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

Terri Talks

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Message from the Director

This month's message comes not from the Director, Terri Gleason, but instead from VA's Deputy Chief Research and Development Officer, Wendy Tenhula.

As of January 31, Terri Gleason, the Director of CSRD, will be retiring from VA ORD service. Terri joined VA Research as one of the first scientific portfolio managers, initially managing both the Behavioral, Psychiatric, and Cognitive Health portfolio and the Aging Research portfolio, back when Clinical and Biomedical were run as Medical Research Service directed by Paul Hoffman. Over time in her VA career, she has served VA Research in a multitude of roles and leadership efforts. She has contributed to many high priority high visibility initiatives on topics that are important to Veterans. From talking to Terri and working with her over the years, I know that she is most proud of the CSRD team she has brought together and who are instrumental in supporting research that makes a difference for Veterans and that she is incredibly grateful for the deep relationships she has established across the VA scientific community. Terri will be missed tremendously, but those she leaves behind will do our best to continue building on the amazing foundation Terri has built in CSRD.

Upon Terri's retirement, current Deputy Director Miriam Smyth will assume duties as Acting Director.

Letters of Intent Numbers Released

The following shows the results of our review of Letters of Intent (LOIs) received November 1 for Clinical Trials and Career Development:

Merit Review Clinical Trial LOIs

Submitted	27
Approved	19 = 70.37%
Disapproved	4 = 14.81%
Disapproved (Other Service)	1 = 3.70%
Disapproved (Standard Merit)	3 = 11.11%

Career Development (CDA-1 and CDA-2) LOIs

Submitted	22
Approved	20 = 91%
Disapproved	2 = 9%

Projects Need to Clear JIT as Transition Nears

As we transition to managing JIT requirements as of January 1, 2022 into eRA JIT, it is critical that projects in VA JIT (from Spring 2021 and older projects in VA JIT) clear. There are 32 CSRD projects (across cycles Spring 2021, Fall 202, Spring 2020) with action needed from the station. Actions include steps that can be taken to meet requirements even before the final assurance document is submitted, such as the PI assurance, other support documents, and miscellaneous documents that can be completed and uploaded for ORD approval while other regulatory documents (IRB, etc.) are still pending committee review. Thank you in advance for clearing any and all outstanding JIT requirements currently in the system as we move to a new, improved model going forward.

Reminder: Clinical Trials Reporting

The Office of Research and Development (ORD) requires the submission of summary results to ClinicalTrials.gov for all of its registered clinical trials. This requirement helps fulfill ORD's commitment to inform Veterans and the public about its research and to maximize the impact of the studies it supports. Failure to properly report results to ClinicalTrials.gov is noncompliant with ORD's funding requirements and may result in current or future project funding to be held or withdrawn by ORD.

Results must be reported through the ClinicalTrials.gov Protocol Registration and Results System (PRS) no later than 12 months after the primary completion date. This is the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome. If the PI anticipates needing an extension for results reporting, they must submit a formal request in the PRS system for CSRD to review.

For VA investigators who are new to the PRS reporting results processes, ClinicalTrials.gov staff members are available to provide one-on-one assistance to investigators throughout the results submission process. This includes helping investigators prepare for submission, orienting investigators to the PRS, and guiding investigators through the data entry process. To schedule an introductory call with ClinicalTrials.gov staff or otherwise request help, send an

email to register@clinicaltrials.gov with the request. Please include a statement that you are a VA ORD-funded investigator, available dates/times (including time zone) for an introductory call and the best phone number at which to reach you.

If you have questions about the process, please reach out to CSRD's clinical trial specialist, Kristina Nord at Kristina.Nord@va.gov.

Summer Research Program Announced

ORD is pleased to announce an opportunity for VAMCs or VA-approved sites to pilot a Summer Research Program (SRP). The purpose of the Summer Research Program is to enhance the diversity of the biomedical, behavioral, clinical, health services and rehabilitative research workforce by providing research experiences and related opportunities that can enrich the pool of individuals from diverse backgrounds, including nationally underrepresented groups, veterans, children of veterans, and disabled individuals who will be available to compete for future research opportunities in the mission areas of importance to the VA.

LOI Submission Instructions

Please submit a letter of intent as an email to VHACOORDDEIWG@va.gov by January 6, 2022. The LOI should include the PI's name, station, and approximate start date for your program. No additional details are required for the LOI.

Proposal Submission Instructions

Please submit the full proposal as a single PDF document from the ACOS/R to ORD Diversity Equity and Inclusion Working Group VHACOORDDEIWG@va.gov by COB on **January 31, 2022**. Applications will be reviewed administratively to determine whether they meet the stated program intent in order to support the proposed program.

Questions? VHACOORDDEIWG@va.gov

CSRD Margin Meeting set for January 12

The CSRD margin meeting for funding decisions will be held January 12, 2022. Please be reminded applicants should not contact Scientific Portfolio Managers until after that date and more preferably after intent-to-fund notifications are sent.

Revised RFA/Diversity Supplements Posted

The revised RFA (RD-22-029) for the 2022 ORD-wide Research Supplements to Promote Diversity was posted on December 14, 2021 and is available at <https://vaww.research.va.gov/funding/rfa.cfm>. The intent of these supplements is to provide mentored research experiences for early career scientists from underrepresented populations. These will be offered as Type 3 supplements to active VA Merits funded by BLRD, CSRD,

HSRD, and RRD, with at least 2 years of funding remaining on the award at the time the supplement is funded.

- **Budget:** \$100,000/yr for up to 2 years
- **Due: February 1, 2022.** One application/yr from each VAMC.
- **Start date: April 1, 2022**
- **Applications will only be accepted through grants.gov and reviewed via eRA commons.**

An informational webinar and Q&A on this supplement opportunity was given on Thursday, December 16, 2021. The webinar recording, webinar slides and a link to the RFA is posted at: <https://www.research.va.gov/funding/diversity.cfm>

For more information: Carol.Fowler@va.gov or VHACOORDDEIWG@va.gov

Barnwell Award Ceremony is January 27

Dr. Louis Dell'Italia will be presented CSRD's highest honor for clinical research contributions, the John B. Barnwell Award, in a ceremony planned locally at the Birmingham VA Medical Center on January 27. ORD dignitaries who will be attending include Drs. Wendy Tenhula, Miriam Smyth, and Mark Roltsch. We are extremely proud to confer this award for Lou (also ACOS/R!) and looking forward to an in-person celebration.

New 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, 2022.

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\[1\]awards.cfm?_ga=2.56572011.1990953416.1542631466-377307463.1536175624#barnwell](https://www.research.va.gov/services/csrd/research[1]awards.cfm?_ga=2.56572011.1990953416.1542631466-377307463.1536175624#barnwell)

CSRD Staff Highlight:



CSRD Scientific Portfolio Manager Mark Roltsch (top right) and others hosted a holiday party on December 16 (in-person and virtually) for CSRD and ORD.



**Warmest Wishes
for the
Holiday Season
from CSRD!!!**

DMC Members Needed

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 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

Newsletter: Lucindia.Shouse@va.gov
