



U.S. Department of Veterans Affairs

Veterans Health Administration
Office of Research & Development

Field Conference Call – Meeting Notes Monday, June 21, 2021 at 1:30 pm ET

1. Welcome

Grant Huang, MPH, Ph.D.

Grant Huang welcomed attendees and highlighted ORD's efforts for VA Research to become more enterprise-oriented by pointing toward agenda items in that context.

2. ORD / Research Enterprise

- GS14 and above centralized promotions process Carol Fowler, Ph.D.

VA ORD announces that submissions for Centralized Positions at GS 14 and above will be moving to the IRBNet platform starting June 30.

All nominations must be submitted to the VA Central Office Centralized Positions Panel via IRBNet at <https://gov.irbnet.org> starting June 30, 2021. Please note: All nominations for centralized positions must be initiated and submitted by the local VA R&D Service and not by the nominee.

A training webinar will be held on June 23, 2021 at 11 AM EDT. An email announcement with meeting details went out to the field R&D Services last week. Please contact Carol.Fowler@va.gov for more details regarding the webinar.

Copies of the new instructions, FAQs and the June 23 webinar recording will be available on the Centralized Positions website

at: https://www.research.va.gov/resources/centralized_positions.cfm

- Cooperative Studies Program
Clinical Research Pharmacy
Coordinating Center

Todd Conner, PharmD
Director CSP Pharmacy
Coordinating Center

An overview of the Cooperative Studies Program Clinical Research Pharmacy and its efforts in supporting both VA and non-VA clinical trials was described. Slides are provided as an attachment to these notes.

3. Research Protections & Policy

Molly Klote, M.D., CIP

- a. There is a new Research Document Finder Tool (webinar early July), to help policy makers and the field find relevant policies related to research within VHA. This tool will have a complimentary FAQ and consult portal tool that is being developed for release in late August.
- b. Biosafety support is now available through our TJFACT contract. An announcement was sent via email, but not one request has yet been submitted. Just want to reemphasize.

Announcement:

The VHA Office of Research & Development (ORD) is pleased to announce that inquiries associated with VA laboratory biosafety and biosecurity (BS&S) activities can be directed to the following email address: VHACOORDBiosafety@va.gov. Our subject matter experts will provide responses on laboratory research topics related to BS&S risk assessment, handling and management of infectious microorganisms, biohazard and chemical waste management, personal protective equipment (PPE), and general biosafety and biosecurity best practices. As a reminder, BS&S related questions should initially be addressed to your local biosafety officer and/or local research safety committee. We look forward to continuing to support the important research work you provide.

- c. New Research and EHRM newsletter – ORD is transitioning from the COVID newsletter to a more diverse newsletter on issues that are happening. There is also the VAIRRS newsletter and a new EHRM update newsletter. We are working to streamline into perhaps one communications tool. Bear with us as we are trying to give you all the information you need, when you need it.
- d. VA Electronic Determination Aid (VAEDA) a decision support tool for research/mot research/exempt determinations is going through its soft launch starting with a webinar for the selected sites on June 24th. More broad launch is anticipated after the validation testing in late July.

4. Finance

Allen Dunlow

Mr. Dunlow attended his last ORD Field Call. He will be retiring on 30 June 2021. His final comments reminded the field that their first fiscal priority is to not allow any funding to lapse. There is currently about \$24M of prior year funding out in the field that needs to be executed. He encouraged the field to not wait until the last minute to execute those funds. He also reminded the field that their second fiscal priority was to minimize carryover. He thanked the field for their aggressive review of their program and identifying funds which could be returned to ORD and reallocated for other

requirements. Mr. John Verwiel will serve as the Acting ORD Director of Finance pending a replacement for Mr. Dunlow.

5. IT Updates

Carl Grunfeld, M.D., Ph.D.

We will be soliciting information over the next few months to increase IT support as part of the move to enterprise help in the field. We may ask you about what modules of SAS or similar statistical software you use, what common software you use and what equipment you have that you would like to put of the internet.

6. WinRMS Training

Tony Laracuenta

WinRMS training is ongoing. We have had two sessions and will have two more upcoming. These trainings are geared to users of WinRMS and provide a more in depth look at how th program should be used. The audience for the training should be AOs and Budget Analysts/Office Staff.

WinRMS is the Research Management System which is a tool to download from the VA Financial Management Systems and allows the program to manage by account.

7. Service Updates

- For all ORD services

Notes Regarding eRA:

- **Use of Internet Explorer (IE) for eRA Modules to be Phased Out by July 19, 2021.** In the wake of Microsoft discontinuing support for IE by August, [eRA will phase out the use of IE](#) for its modules by July 19, 2021 due to security concerns. Please switch to other eRA-supported browsers. See [Tips & Tricks for Fixing Browser Configuration Issues When Using eRA Modules](#) webpage for common situations users may experience.
- The NIH has announced a new eRA Commons login option. **All users will be required to switch by September 15, 2021.** Please visit their web page [Two-Factor Authentication: Accessing eRA Modules via login.gov](#) for details.

- BLR&D Updates

Christopher T. Bever, Jr., MD, MBA

A reminder that investigators and stations should not contact SPMs about proposals in review until after the margin meeting which will be on July 14 and 15.

- RR&D Updates

Patricia A. Dorn, Ph.D.

Paul B. Magnuson Award:

The Paul B. Magnuson Award is presented annually to a VA RR&D investigator who exemplifies the entrepreneurship, humanitarianism, and dedication to veterans displayed by Dr. Magnuson during his career. The award was established in 1998 in recognition of the importance of rehabilitation research within the VA Health Care System. The award consists of a one-time \$5,000 cash award to an individual, \$50,000 per year for 3 years supplemental funding for their ongoing peer-reviewed research, and a celebratory plaque.

Nominations for the 2022 Paul B. Magnuson Award are being accepted through September 1, 2021. Please refer to [Program Guide 1203.06](#) and the [Instructions for Preparing and Submitting a Nomination Packet](#).

Review Updates

New LOI and Waiver Process:

ORD has been working with the NIH to develop capabilities for VA to accept Pre-applications through eRA Commons. The first use of Pre-application will be for LOI and waiver submissions to RR&D for the Fall 2021 SPiRE cycle.

Scientific Review Timelines (refer to applicable [FOA/RFA](#) for details):
Please continue to contact [RR&D](#) for guidance and to ask questions.

Spring 2021 – SPiRE:

- NEW RFA published – December 22, 2020
- LOI and Waiver Request deadline – February 1, 2021
- Last possible application submission deadline (no changed/corrected applications after this date) – March 10, 2021
- Scientific Review – April 22, 2021
- Scores and Summary Statements released – May 12, 2021
- Intent-to-Fund notifications – June 21, 2021

Summer 2021 - Merit, Career Development and Research Career Scientist:

- Updated RFAs published – March 30, 2021
- LOI and Waiver Request deadline – May 3, 2021 (May 1 falls on a Saturday)
- Last possible application submission deadline (no changed/corrected applications after this date) – June 10, 2021
 - NOTE: Biographical Sketch Format (OMB No. 0925-0001 and 0925-0002 (Rev. 12/2020 Approved Through 02/28/2023) must be used)
- Scientific Review – August 5-13, 2021
- Scores released – August 17, 2021
- Summary Statements released – September 7, 2021
- Intent-to-Fund notifications – by late September 2021

Fall 2021 – SPiRE:

- NEW RFA published – by July 1, 2021
- Pre-application (LOI and waiver request) deadline (no changed/corrected applications after this date) – August 2, 2021

- Last possible award application submission deadline (no changed/corrected applications after this date) – September 10, 2021
 - NOTE: Biographical Sketch Format (OMB No. 0925-0001 and 0925-0002 (Rev. 12/2020 Approved Through 02/28/2023) must be used)
- Scientific Review – October 22, 2021
- Scores and Summary Statements released – November 12, 2021
- Intent-to-Fund notifications – by late November 2021

- HSRD & QUERI Updates

Naomi Tomoyasu, Ph.D.,
David Atkins, M.D.,
Amy M. Kilbourne, Ph.D., MPH

- National HSRD Meeting/CDA meeting
HSRD cannot predict what environmental factors will influence face-to-face meetings this fall. HSRD, however, proposes proceeding with:
 1. Plans for a virtual CDA meeting in October
 2. Submitting proposal for national in-person meeting for July 2022.
- Waivers for enrolling non-Veterans:
Many of you were required for first time to request waivers to include non-Veterans in your research studies. The origin of this is concern over liability for side effects arising from clinical research. Nearly all of the HSRD waivers involved minimal risk studies that include clinicians or other staff as research subjects. In the future, we will not request waivers until projects are funded (i.e. in JIT) and we will ask ORPPE for an exemption for minimal risk studies.
- HR updates—Scientific Program Manager (SPM) backfills for George Fitzelle, Miho Tanaka and Nsini Umoh- plan to identify candidates in the next 3-4 weeks.

Temporary coverage (through summer) of portfolios:

- Women’s Health/Health Equity — Bob O’Brien
- Aging/LTSS — Rob Small
- Social Determinants of Health — Emily Evans
- Informatics/Big Data/Virtual Care — Stephen Marcus
- HSRD Diversity, Equity and Inclusion Workgroup — Naomi Tomoyasu

- QUERI Updates

FY21 budget changes and/or returned funds due by July 23. If you have any FY21 changes that affect your budget (e.g., changes in distribution of funding across sites, returning funds), submit these changes via the [ORD Finance SharePoint site](#) (if returning funds or changing the distribution of funding

across existing sites) or by submitting a project modification form (for all other changes, such as adding a site) to Melissa by July 23.

Make sure to spend all your FY21 funding by September 30, 2021 or return your funds by July 23, 2021. Any funding not spent will be swept at the end of the fiscal year.

QUERI Implementation Strategy Learning Hubs. QUERI's learning hubs provide a unique opportunity for leaders, providers, and researchers across VA to gain the practical experience and skills needed to lead care improvements at their sites. Specifically, HSR&D/QUERI investigators can learn how to deploy rigorously-designed implementation strategies in their own studies. Each Hub follows the general framework of the QUERI Implementation Roadmap and teaches specific implementation strategies for different settings. Check out the [QUERI website](#) to learn more!

QUERI ADIL RFA updated May 28. Make sure to review the updated QUERI ADIL RFA posted on the [QUERI website](#). The yellow highlighting signifying updates has been removed because we received feedback that the highlighting was confusing, so we have highlighted the two key updates below.

- Page 1
Potential candidates for this award include:
 - Early career investigators (e.g., MD, DO, PharmD, PhD, DNP, or equivalent degree in their postdoctoral phase of their scientific career) who have not received and are not currently applying for independent project funding (e.g., HSR&D IIR, QUERI PEC) as a principal investigator (PI)
 - Pages 3-4
Submit only the materials listed below; additional items/appendices will not be accepted for first submissions. If a reviewer specifically requests additional item(s) (e.g., interview guide) in reviewing the first submission, then the resubmission can include the requested appendix item(s).
 1. Introduction to Revised Application (for resubmission only; 2-page limit) The substantial scientific changes must be marked in the text of the application by bracketing, indenting, or change of typography. A vertical bar drawn in the margin may be used as long as changes in text are also indicated by bracketing, indenting or change of typography. Do not underline or shade the changes. Deleted sections should be described but not marked as deletions. If the changes are so extensive that essentially all text would be marked, explain this in the Introduction.
- VINCI's scope has increased over the years to support other research service lines and will be transitioning from an HSR&D resource center into ORD aligning with the ORD strategic priority to Put VA Data to Work for

Veterans. This transition should not change what is available to COINs and other HSR&D users of the VINCI environment, data, tools, or services. This move is part of ORD's enterprise planning that is anticipated to address research's increasing growth and computational demand – exciting things are in the works. There will also be time to receive your feedback and discuss any concerns about the transition, including VINCI's continued commitment to serving the HSR&D community.

- Recipients of the 2020 HSR&D Field-Based Awards

Best Research Paper of the Year Award:

Yancy, William (Durham COIN)

Health System Impact Award (joint 3-way):

Klap, Ruth (Greater LA COIN)

Hagedorn, Hildi (Minneapolis COIN)

Gordon, Adam (Salt Lake City COIN)

Daniel Deykin Award:

Chinman, Matthew (CHERP-Pittsburgh COIN)

- CIDER –In Progress: [Advancing VA Telehealth and Virtual Care](#)

Veterans' Perspectives: [Veterans' Perspectives on Wellness Guide](#)

ESP Report: [Hospitalized Adults](#)

[Medical Care Supplement Highlights Research on VA Community Care](#)

In this Supplement, 12 articles highlight research focusing on Veterans' use of community care and how VA facilities interact with community care (CC) providers. The Supplement offers a broad examination of VA's expanded Community Care program, with articles on topics such as: comparing wait times for specialty outpatient services in CC and VA; comparing Veterans' use of primary care services at VA facilities versus CC; and examining the challenges VA medical centers face in their relationships with engaging community providers in care.

- **CDA updates**

Rob Small will be the SRO on HSR6 (long-term care & aging) in addition to the mentored research panel for the upcoming SMRB. While HSR&D works to fill 3 vacant SPM slots, Rob has been given a 120-Day promotion to handle the portfolio left by Nsini Umoh, who recently accepted a position at NIH.

Nominations for Research Career Scientist awards will be accepted for the September 1 deadline. The updated RFA will be posted by the end of June.

GS14/15 field promotions received in March 2021 are on route to CRADO for signature.

Rob has been part of a cross-service ORD workgroup to improve the GS14/15 promotion process. A major advancement that is in the final stages of implementation is the adaptation of IRBnet to receive and review promotion packets. The system will be on-line for the September round of promotion packet, and will be tested earlier this summer by BL/CSR&D.

- SMRB Update

Summer 2021 Cycle

On May 23, 2021, HSR&D revised all of the posted Summer 2021 RFAs to reflect the new HSR&D policy on non-VA Co-investigators. Non-VA investigators who have an MD/PhD equivalent are eligible to serve in the role of Co-investigator, but they cannot be listed as such on the budget forms. Additional details are in the posted RFAs.

The HSR&D Intent-to-Submit in ART opened **April 23, 2021** and closed on **May 7, 2021** (at 8:00 pm EST).

209 ITS were received for HSR&D.

The first day to submit full applications (using Grants.gov Workspace or eRA ASSIST) is May 15, 2021 and the last possible submission day is June 10, 2021.

HSR&D's Scientific Merit Review Board and Career Development Award review meetings are both scheduled to take place virtually August 24 - 27, 2021.

For questions regarding the review process, please contact Scientific Merit Review Program staff at vhacoscirev@va.gov

- CSR&D Updates

Terri Gleason, Ph.D.

- Budget execution! CSR&D has received a lot of returned funds from the field during this quarter. In some cases, we were able to provide supplemental funds for projects restarting. We understand the specific challenges to clinical research due to the pandemic, however at this point, effective today (6/21/21) we will not accept further returns, and will ask research offices to continue to try their best to obligate funds on station this fiscal year.
- We are reporting on the results of our reviews of Letters of Intent for both Career Development and Clinical Trial applications considered in advance of the Fall

2021 round submission. Our approval rate remains high, but we still see areas for potential improvement across the field. The disapprovals are mainly focused on issues of eligibility for the award, as well as for clinical trials a continued struggle in terms of overlap with other already ongoing trial activity. While the research office may be able to pre-review on the eligibility issue, we continue to strongly encourage applicants to talk with our SPMS prior to LOI submission to make sure their ideas do not overlap with funded projects. The issue of enrolling non-Veterans with a greater-than-minimal risk procedure proposed has been another reason for disapproval. We hope in all cases that the feedback we provided in any disapproval is clear. Here are the overall results:

CSRD TRIALS LOIs

Submitted	29	
Approved	19	65.52%
Disapproved (other service)	3	
Disapproved (standard merit)	1	
Disapproved	6	
Withdrawn	0	

Career Development

<u>LOIs</u>	<u>CSRD</u>
Received	22
Approved	17
Disapproved	4
To Other Service	0
Withdrawn	1
Approval Rate	77%

- Following in the same vein about consulting with SPMs, we have a lot of expressed interest from stakeholders, including Congress, on particular interventions that have anecdotal evidence of effectiveness for certain priority areas. In most cases we have developed a strategy for making funding decisions in priority order and in some cases using roadmaps which we will continue to disseminate. I'd highlight some of the hot topic interventions which we need to be very strategic about, and they include: ketamine and esketamine, psychedelic drugs, and medical marijuana comprise the most common queries. If there are questions about any of these, please have applicants reach out to us in advance of expending effort on applications of any size or type.
- COVID-19 Clinical Trials. I'd like to update the field on the general direction we are going in regarding clinical trials focused on prevention and treatment for

COVID. We have found the field to be highly responsive to calls for trial sites and other related activities. However, VA sponsored trials have been highly challenged to complete as we see the more positive turn to reduced cases and increased vaccination. Our goals going forward for trials will be to support VA contributions through partnerships wherever possible, including of course other federal agencies where we already have established relationships. This detail is being provided for everyone to have a general sense of how we will be supporting VA contributions for trials through partnerships. Please expect more details to follow as we establish the partnership pathways, as always please reach out if you have questions.