



U.S. Department of Veterans Affairs

Veterans Health Administration  
Office of Research & Development

## Field Conference Call – Meeting Notes Monday, September 20, 2021 at 1:30 pm ET

Internal Teams Site: [Click Here](#)

### 1. Welcome

Rachel Ramoni, DMD, ScD

Dr. Ramoni welcomed attendees and highlighted the full agenda, many of which focused on enterprise efforts.

### 2. ORD / Research Enterprise

Grant Huang, MPH, Ph.D.

- NAVREF Annual Virtual Conference materials

There are still a few ORD paid licenses available for individual interested in accessing recordings and other meeting materials from the NAVREF/ACOS-R meeting held on Aug 23-25. Interested individuals should have their ACOS-R or AO send Grant one email on behalf of their facility indicating names/emails for those wanting access. Requests will be approved on a first-come, first-served basis until no more licenses are available.

- Updates for Centralized positions

Carol Fowler, Ph.D.

Nominations for appointments at GS 14 and 15 are now being submitted exclusively on gov.IRBNet as of 6/30/2021. Updates to the promotions coversheet wizard were made on gov.IRBNet on Friday, 9/17/2021. For ease of use, the non-VA funding and funding history sections were removed from the coversheet and will now be submitted as additional documents. Updated instructions will be attached to the call notes and can be found at: [https://www.research.va.gov/resources/centralized\\_positions.cfm](https://www.research.va.gov/resources/centralized_positions.cfm)

- Research Enterprise Spotlight - Million Veteran Program (MVP) - Sumitra Muralidhar, Ph.D.

An overview and update were provided on MVP. Slides are provided as an attachment on the internal ORD Teams site. The discussion focused on: aims to improve Veterans' health by incorporating genetic, lifestyle, military exposure and health information and providing precision healthcare/medicine; efforts to enroll at least one million Veterans in MVP; establishing a comprehensive database of genetic, lifestyle, military experience and health information as a scientific discovery platform to drive precision healthcare/medicine for Veterans and the nation; and establishing pipelines to translate scientific discoveries from MVP into the clinic.

### **3. Research Protections & Policy**

Molly Klote, M.D., CIP

- VAEDA (VA electronic Determination Aid) –

A soft launch underway as of September 8. 8 facilities are participating: Albany, Ann Arbor, Boston, Charleston, Indianapolis, Phoenix, Pittsburgh, San Francisco. Expect full roll out in November 2021.

- CIRB support contract

A 6 new IRB managers and a 2 person helpdesk will be provided. Contract will be awarded by September 30<sup>th</sup>. Expect to start by late October.

- DocuSign envelopes

Please encourage the use. We have 60,000 unused envelopes so far. 175 projects and 40,000 envelopes have been approved.

- CTMS update

A sandboxing demonstration of 6 systems and requirements creation was completed. Also, an acquisition packet was created. ORD expects contract in place by mid-October.

- Proactive calling SharePoint site

A resource for the field is expected launch by Sept. 24<sup>th</sup>.

### **4. Finance Updates**

John M. Verwiell

Prior Year unobligated balance stands at \$1.8M and Current Year unobligated balance is \$197M. This is an improvement from last week and better than the previous FY. 7 large contracts remain to be obligated for Enterprise operations. Over the past several days, \$29M in contracts have been awarded.

The Continuing Resolution period has not been solidified but December 3<sup>rd</sup> was date set by the House.

### **5. ORD Field Update newsletter**

Mitchell Mirkin

All VA research is intended to ultimately contribute to the health and well-being of Veterans. Link below highlights examples of how VA research has been translated into everyday health care within VHA or in medical care generally.

[https://www.research.va.gov/pubs/ord\\_field\\_update/default.cfm](https://www.research.va.gov/pubs/ord_field_update/default.cfm)

ORD Communications asks for your support in making the monthly newsletter *ORD Field Update* a valued source of information on new funding opportunities, opportunities for collaboration, and other areas. We welcome your feedback, input and participation, and hope this newsletter will effectively address your needs and reflect your interests. Best contact: [Tristan.Horrom@va.gov](mailto:Tristan.Horrom@va.gov) (editor).

## **6. Field IT updates**

Carl Grunfeld

Please encourage all of your researchers to fill out the software survey (only the recipient can use their link). Listing software will allow decision about enterprise resource support of software and will signal OIT about research specific software that will cause problems if they remove it.

If you have an affiliate that uses EDUROAM and you do not have a guess wireless that allows you to use affiliate computers to access affiliate sites, please e-mail me.

## **7. Updates on WinRMS and Training**

Tony Laracuente

- WinRMS

Several weeks ago, an email was sent out an email regarding the Research Support Division (RSD) work with the RDCC to allow the RDCC team access to WINRMS computers for new installations, updates and fixes. The RDCC has not been able to do installs without the help of local OIT. The RSD has developed a process whereby the RDCC can bypass local OIT and do the install/updates directly, thus making this more efficient. A group has been setup at each facility that has WINRMS active. If your local OIT is having issues supporting the move of the WinRMS computers to the new group then please email Tony Laracuente so he can advise RSD. It is hoped to have all computers moved by the end of month.

- Training

Next week ORD will be hosting two trainings. The first is on closing and opening fiscal years as well as guidance on expectations regarding FY22. This training will be held on September 28 at 2 pm. An announcement will go out this week.

The second is the year end RAFT expenditure report which is due October 15. It is critical to have the report be as accurate as possible. The training will occur on both the 29<sup>th</sup> and 30<sup>th</sup>. You only need to attend one session.

## **8. Service Funding Opportunities, Reviews and Updates**

- Cross services announcements / eRA updates

Wendy Tenhula, Ph.D.

- New ORD wide requirement for VAMC Directors Letter in Applications (applies to all four services)

ORD continues to be highly supportive of protecting clinicians time on funded research. We will remind all that the VA on Directive 1605 includes a description of what would be considered standard practice for research: [VA ORD Guidance for Protected Time for Research Staff](#) . The link referenced appears on the OPES website with Directive 1605, as well as our ORD website under Administrative Resources. Additionally, we have started conversations to continue to uncover ways to support this important aspect of clinicians actually being able to complete their funded research with the protected time. In this regard, a new requirement has been proposed and accepted by ORD Services. That is we will be asking for a new element to be included in the VAMC Director's letter which is required for submissions under our Requests for Applications (RFA). This language will state, **"If the PD/PI is a clinician, a statement committing support from the facility to cover clinical effort impacted by the proposed research effort as needed for the project (up to 3/8ths, Reference from VA Handbook: [VA ORD Guidance for Protected Time for Research Staff](#) )."** We feel like this will be an additional indication of support for the clinician role, and hope that this helps in securing the intent – that clinicians have an agreement up front before application submission from the local facility. Please note this new requirement will be implemented for the winter review round starting with HSRD and RRD applications due Dec 15. We will remind stations of the need to include this detail in VAMC Directors Letters going forward. We will update the VA Application Guide SF424 (R&R) with this new requirement for the Winter cycle. The anticipated publication date is October 1.

- Update: Notification of Upcoming Change in Federal-wide Unique Entity Identifier Requirements [NOT-OD-21-170](#)

- BLR&D Updates

Christopher T. Bever, Jr., MD, MBA

#### Fall Review Round

Completed applications were due in eRA by 6pm on Sept.10 with no review time. Proposals are currently undergoing administrative review and committee assignment. Questions can be directed to Dr. Mike Burgio, Review Manager.

#### Spring submissions:

The deadline for Letter of Intent for the spring round is November 1.

#### Field-based planning meetings

BLRD will again be supporting field-based planning meetings in 2022. The funding opportunity announcement was posted at the end of August with an application deadline of October 31. The purpose of the meetings is to allow groups of investigators to plan collaborative studies with clear translational goals. The meetings may be in-person, virtual or hybrid.

#### Clinician Scientist Award Extension program

A reminder that field stations can nominate outstanding clinician scientists with outstanding scores on their Merit Award renewal applications for this program which provides a two-to-four-year award extension.

#### Workshop on micro physiological systems

As part of the Congressionally mandated VA five-year plan to eliminate or reduce the use of sensitive animal species in VA research we are working with the National Center to Advance Translational Research on a workshop on using micro physiological systems to replace animal models. The workshop will focus on VA investigators who are currently using or are planning to use dogs, cats or non-human primates in their research and is tentatively planned for November, 2021. Contact Dr. Arun Sharma for details.

#### Spring 2021 RCSR Committee Review

System generated intend-to-fund notices were distributed on Sept. 3. Stations and PIs will be receiving the usual field notification letters from the BL and CS Service Directors shortly. Please note the new feature attached to the field notification letters. For each candidate reviewed, there is a Summary of Discussion document attached that will help explain the score-driving-factors and decisions from the RCSR Committee.

#### 2022 Middleton Award

Nominations for the 2022 Middleton Award are due in ORD – **February 1, 2022**. The nomination instructions can be found on the website for the Middleton award and a link will be included in the field conference notes. The **Middleton award**, BLR&D's highest honor for outstanding scientific achievement. We are looking for VA scientists whose research program has had a substantial real-world impact on the healthcare of Veterans. The nominee should stand head and shoulders above his/her peers in terms their impact on a research field of prime important to VA's research mission. Middleton Website: [William S. Middleton Award \(va.gov\)](http://www.va.gov)

- CSR&D Updates

Terri Gleason, Ph.D.

#### Program for Collection of Biospecimens in CSR&D Clinical Trials

The Clinical Science Research & Development Service (CSR&D) is announcing an opportunity for VA investigators to request support for the collection of biospecimens in

CSRD-funded clinical trials. This program is initially being made available as a supplement to ongoing trials, irrespective of topic area. This opportunity is available only to studies that will generate a minimum of 100 specimens.

This program involves a collaboration between the CSRD Service and the VA Science and Health Initiative to Combat Infectious and Emerging Life-Threatening Diseases (VA SHIELD [add link](#)). A centralized biorepository, managed by the VA SHIELD coordinating center, is part of a program-wide effort to standardize the methods for research with, and storage of, biospecimens across VA studies focused on the broad range of diseases/conditions of significance to Veterans.

The biospecimen repository will enable generation, storage, and analysis of molecular and other associated data making it available for research to advance scientific understanding in support of improving diagnosis, treatment, preventative strategies, and outcomes of care for Veterans.

If approved for funding, CSRD will provide guidance related to the National Multicenter VA Specimen Collection Protocol for VA SHIELD which has been approved by the VA Central Institutional Review Board (CIRB). VA SHIELD will provide protocols/training on sample collection, consent form, processing, local storage, and shipping to ensure standardization and consistent specimen quality.

**Mechanism.** CSRD will provide supplemental funding to ongoing CSRD clinical trials for costs associated with collection of biospecimens, pre-processing, storage at generating VA facility, and shipment to VA SHIELD biorepository. Once stored within VA SHIELD, the study PI will be provided with guidance on planning for future analyses and accessing specific trial specimens/data.

### **Application Requirements.**

Applications must consist of:

1. A one-page **CSRD Biospecimen Supplement Summary** to include:

**Background.** Provide relevant background information including a brief description of the specimens to be collected, type of biomarkers to be analyzed and their potential relevance.

**Approach.** Summarize the study design and the approach to identifying and confirming clinically relevant biomarkers as diagnostic, prognostic, and therapeutic indicators in diseases/disorders relevant to Veterans.

**References.** Provide key relevant references.

Please use typeface Arial, Georgia, Helvetica, or Palatino Linotype with font size 11 points or larger.

2. The completed **CSRD Biospecimen Intake Document** (*Attachment 1*),
3. A **summary budget worksheet** indicating the budget request (*Attachment 2*). Allowable budget items include: salary support for a staff member to collect/store/package samples, supplies for specimen collection, storage, and shipping, etc. The budget is not capped but is expected to strongly justified.
4. **Budget justification** (*Attachment 3*). One page limit.

### **Submission.**

Applications (consisting of the summary document and Attachments 1-3 combined into a single PDF) should be submitted by the PI's local VA Research Office via email to [VHABLRD-CSRD@va.gov](mailto:VHABLRD-CSRD@va.gov). The email should have the following subject line: "CSRD Biospecimen Supplement Request" and should contain a statement from a representative of the R&D Service (with title) confirming the availability of VA space to manage the requirements related to the collection and storage of samples until shipped to VA SHIELD. Incomplete applications or applications submitted directly by the PI will be returned without review.

### **General Criteria for Review and Scoring of Supplement Requests.**

CSRD staff will conduct first level review of biospecimen supplement requests based on criteria including the generation of clinically relevant biomarkers as diagnostic, prognostic, and therapeutic indicators in diseases/disorders relevant to Veterans and capacity to share specimens and study data for future analyses by other ORD PIs (after an embargo period when the PI and study team have priority). Second level review will be conducted by the VA SHIELD Programmatic and Scientific Review Board, which will recommend approval/disapproval to the Director/CSRD.

### **Timeline for Submission and Review.**

CSRD will accept applications at any time until further notice. Awards will be announced on a rolling basis.

- HSRD & QUERI Updates Naomi Tomoyasu, Ph.D.

### HR Updates

- *Posted GS12-13 Management and Program Analyst:* HSR&D has begun interviews and are on schedule to select the best candidate for the Management and Program Analyst by the end of this month.
- *GS 14:* This position is for the Scientific Project Manager for the following HSRD portfolios and activities: women's health, health equity, rural health and other initiatives/projects as assigned (e.g. PROVEN, special COVID projects, high

priority needs for special populations etc.). HSR&D has posted this SPM ad internally within ORD and will post it on USAJOBS.

- *GS 13 Health Science Specialist (vice Emily)*: We are awaiting approval for this position and hope to post ad in about a month or so.
- *AAAS Fellows Onboarding*: HSR&D welcomes two new Fellows: Drs. Karen McNamara and Laura Zimmerman, both of whom have started on September 13, 2021.

### Merit Review Cycle

#### *Summer 2021 Cycle*

- HSR&D's merit review meetings took place virtually on August 24 - 27, 2021. Scores were released on September 1, 2021.
- Summary statements are expected to be released in **early October**. Funding decisions are expected to be made in **late October** and Notices of Intent (To-Fund or Not-To-Fund) will be sent at that time.

#### *Winter 2022 Cycle*

- New and revised RFAs are expected to be posted on or around September 23, 2021 on the intranet site. Please review the RFAs thoroughly to check for any changes in requirements and to ensure compliance.
- The HSR&D Intent-to-Submit in ART will be open from **October 21 to November 4** (at 8:00 pm EST).
- The first day to submit full applications (using Grants.gov Workspace or eRA ASSIST) is November 15, 2021, and the last possible submission day is December 10, 2021.
- HSR&D's Scientific Merit Review Board and Career Development Award review meetings are both scheduled virtually to take place March 8 - 11, 2022.

For questions regarding the review process, please contact Scientific Merit Review Program staff at [vhacoscirev@va.gov](mailto:vhacoscirev@va.gov)

- RR&D Updates

Patricia A. Dorn, Ph.D.  
Karen Lohmann-Siegel

Welcome Dr. Anthony Pacifico to RR&D





The Rehabilitation Research and Development Service (RR&D) is delighted to welcome Dr. Anthony Pacifico as the Scientific Program Manager for the Brain Health and Injury portfolio. Dr. Pacifico has a Ph.D. in Biochemistry from the Graduate School of the City University of New York. His thesis research developed infrared imaging tools for use in pathology followed by a postdoctoral fellow position at the National Institute of Alcohol Abuse and Alcoholism (NIAAA). His research at NIH/NIAAA examined the molecular signaling processes involved in night vision using a variety of biophysical tools. Prior to joining VA, Dr. Pacifico was a Program Manager with the Department of Defense at the Congressionally Directed Medical Research Programs. There, he led efforts in Alzheimer's disease research to better understand Traumatic Brain Injury (TBI) as a risk factor for neurodegeneration. In addition, he stood up the Epilepsy Research Program (ERP) looking exclusively at the relationship between TBI and Post-Traumatic Epilepsy (PTE), from developing animal models of PTE to conducting epidemiological studies. Dr. Pacifico was born in Queens, New York, but was raised on the west side of Manhattan; as such, he is by default (but not a devout) Mets fan. He lives in Germantown, Maryland with his wife and two children. He enjoys hiking/biking the C&O Canal and hopes to complete the entire length one day. He listens to music of all types, with some modern-day exceptions. He also enjoys food of all types, but is still looking for a great slice of pizza in the D.C. area!

#### RR&D Research at Louis Stokes Cleveland VAMC Featured on PBS NEWS HOUR



Dr. Dustin Tyler's research program on returning sensation to touch for Veterans who have experienced limb loss, aired September 1, 2021, on the PBS News Hour as part of their Breakthrough Series on innovation and invention. Dr. Tyler is a VA Research Career Scientist, Director of Engineering, Quality and Regulatory Affairs for the RR&D Advanced Platform Technology Center, and Kent H. Smith II Professor of Biomedical Engineering at Case Western. Dr. Tyler is an expert in neuroscience, neural interfacing, and neural prostheses.

Watch the video here: <https://www.youtube.com/watch?v=9vtcmZai3yl>

For More Information: [Dustin Tyler, PhD - Advanced Platform Technology Center](#)

#### GENERAL ANNOUNCEMENTS:

Review Updates:

**SCIENTIFIC REVIEW TIMELINES** (refer to applicable [FOARFA](#) for details):  
Please continue to contact [RR&D](#) for guidance and to ask questions.

***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 – June 30, 2021
- Pre-application (LOI and waiver request) deadline – 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

***Winter 2022 - Merit, Career Development and Research Career Scientist:***

- NEW RFAs published – by October 1, 2021
  - NOTE: An updated VA Application Guide SF 424 (R&R) will also be published by October 1
- LOI and Waiver Request deadline – November 1, 2021
- Last possible application submission deadline (**no changed/corrected applications after this date**) – December 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 – February 22 thru March 2, 2022
- Scores released – March 4, 2022
- Summary Statements released – March 25, 2022
- Intent-to-Fund notifications – by early April 2022