



U.S. Department of Veterans Affairs

Veterans Health Administration
Office of Research & Development

Field Conference Call – Meeting Notes Monday, October 18, 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, PhD

- Blood collection tubes shortage

ORD was recently made aware of a national shortage on blood collection tubes that may have implications for VA research. Guidance is being drafted and will be shared as soon as possible.

- Research Enterprise Spotlight

VHA Regulatory Research Cybersecurity Guidance – DuJuan Williams
Carol Johnson

- An overview of the OIS VHA Regulatory Research Cybersecurity Guidance Request Process & ServiceNow (yourit) Intake Portal was provided by the OIT Research Support Division (see attachments). This portal is intended to:
 - Establish a primary complimentary resource for research stakeholders requesting research information security and cybersecurity support services through the development of the OIS VHA Regulatory Research Cybersecurity Guidance Request Process & Intake Portal.
 - Streamline the process for triaging, evaluating, and responding to research stakeholder's request for information and guidance regarding a research project's compliance with VHA/VA regulations, directives, and cybersecurity/information security policies through the [VHA Regulatory Research Cybersecurity Guidance ServiceNow Catalog](#).
 - Increase awareness of processes that help address research-specific information security needs and requirements utilizing the [RSD Regulatory Research Cybersecurity Guidance Portal](#)

- Technology Transfer Program (TTP) updates

John Kaplan, PhD, JD, PE

TTP had a number of key accomplishments. Included are:

- Record numbers for VA Invention Disclosures (744), licenses (10) and royalty revenue (\$3.1M)
- Several firsts including a Knowledge Management System in Commercial Cloud (first in the federal government); the first VA Federal Lab Consortium Award
- Mr. Ryan Davis was acknowledge as a Technology Transfer Rookie of the Year
- Additionally, Field Technology Transfer Specialists were highlighted at current sites in Atlanta; Tampa; Cleveland; Palo Alto; New York City.
- Future sites planned include: San Diego; Houston; Seattle; Chicago; Ann Arbor; Indianapolis; Baltimore; Utah; West Haven; Nashville; Charleston, SC
- Reminders were given that investigators and R&D Offices should continue to be diligent in their reporting responsibilities for FY22 to continue contributing to these successes.
- Data on VA Certification Forms that are Missing or Incomplete is below. Assistance in getting these done was requested.

	Number of Inventions Disclosed to TTP	VA Certification Forms Missing or Incomplete 12 August 2021	VA Certification Forms Missing or Incomplete 12 October 2021
FY14	290	1	1
FY15	219	1	1
FY16	241	0	0
FY17	589	3	3
FY18	496	2	2
FY19	724	32	32
FY20	625	28	22
FY21	744	226	151
Total Missing or Incomplete Certification Forms		293	212

3. Finance Updates

John M. Verwiel

Information was provided on the following:

- Execution Plan based on the RAFT report was presented including action that will be required from R&D Offices for plans for carryover funds.

- AACS will open up Wednesday October 20th for ITAs to be distributed. Current CR last through December 3rd.
- There currently is a 95% completion rate for RAFT Expenditure report
- Prior Year execution reports are due November 1 on the SharePoint site.
- RDIS reporting now open and info is due no later than November 16

4. 2020 NPC Annual Report

Kimberly Collins

Eighty VA nonprofits have reported their results for last year, 2020. In total, revenues were \$282 million, down by 1% from the previous year. The previous year, 2019, was a record year for revenues, so 2020 was very close to the all-time record for NPC revenues, despite the many serious adversities presented by the pandemic.

Over the past ten years, after paying all of their own administrative expenses, the NPCs have administered \$2.4 billion of VA research funds brought in by VA researchers. The foregoing \$2.4 billion amount administered by the NPCs does not include IPA assignment agreement reimbursements from VA.

The NPCs' estimated net contribution to VA is approximately \$60 million annually. This amount is figured as their administrative expenses (\$40 million) plus amounts expended for VA Research and Education from the NPCs' earnings (\$20 million).

The NPCs employed 2,500 people, supported 2,100 PI's, and administered 3,700 research projects.

Government funding, that is, principally NIH and DoD, was \$197 million (70% of total revenues), up in total by 4% from the previous year. NIH was \$111 million, up by 6% from the prior year. DoD was \$40 million, down by 11% from the prior year. Various state programs decreased by 24% from 2019 to \$8 million. Sixty-seven, NPCs reported revenues from governmental sources.

Non-government funding was \$81 million (29% of total revenues), down by 11% from the previous year. The remaining \$3 million (1% of total revenues) was from interest earnings and other miscellaneous sources. Forty-one of the NPCs recorded revenues from non-governmental sources, including CRADAs, that amounted to half or more of their total revenues. There were 279 distinct sources for non-governmental revenues over \$25,000.

The NPCs submitted 449 CRADAs for approval and actually started 304 CRADAs. New CRADA's started were down by 25% from the prior year. For the third year in a row, Veterans Medical Research Foundation in San Diego started the most new CRADAs, or 19 for 2020.

Six NPCs posted revenue gains of more than \$1 million. The largest single increase was recorded by Institute for Medical Research in Washington, DC (\$3.7 million). Thirty-six locations had revenues increases while 44 locations had lesser revenues than in the prior year.

Included in revenues for the year was \$24 million from VA for IPA assignment agreement reimbursements. Thirty-four NPCs received IPA reimbursements. Of these, eight posted reimbursements of more than \$1 million. The largest amount for any one NPC was \$4.1 million which was paid to the Palo Alto NPC.

Expenses were \$282 million for 2020. Eighty-three percent of expenses were incurred for VA Research. Administrative overhead expenses continued to be relatively low at 16%. Education related expenses were 1%. The NPCs paid \$1.3 million in travel expenses, principally for researchers.

The NPC's managed \$335 million in assets and book net worth across the system was \$214 million before consideration of amounts reserved for research projects. Net worth after consideration of amounts to be expended on research was estimated at \$64 million. Ten NPCs reported that they had less than six months' worth of their administrative expenses in reserve.

Twenty-nine internal control material weaknesses in ten NPCs were reported by independent outside auditors. A few of these were repeat material weaknesses. Two-thirds of the material weaknesses were in the Durham and Denver NPCs. NPPO routinely follows-up to ensure that the reported material weaknesses are effectively remedied. NPPO also follows up upon significant deficiencies and recommendations reported by the outside auditors.

All NPCs that were required to have audits done by independent outside auditors complied with the legal requirements for the audits. Annual report preparation was seriously delayed because approximately half of the individual reports were received late from the NPCs and many contained material errors requiring corrections and re-submissions. Two reports were more than two months late and one was three months late following the June 1 filing date.

5. Field IT updates

Carl Grunfeld, MD, PhD

Appreciation was expressed to those who recently filled out the software survey to help determine needs. This info will be critical in future planning efforts.

6. Million Veteran Program

Suma Muralidhar, PhD

- Data access

Starting with the Spring 2022 cycle for BLR&D/CSR&D and summer cycle for RR&D/HSR&D, any eligible VA investigator can apply for MVP data access through existing ORD mechanisms such as Merit Review and Career Development.

Eligibility criteria and requirement for a LOI or intent to submit will align with Service-specific and RFA-specific requirements.

For the Spring 2022 BLR&D/CSR&D parent merit RFAs, a LOI will no longer be required. Your investigators do not have to submit a LOI by the Nov 1 deadline. Instead, an intent to submit will be required by February 1, 2022 to help the SPMs prepare for review and the MVP program for prepare for centralized computing resources.

Please note that CDA and other special RFAs that require an LOI will still need an LOI as per the deadlines in the specific RFAs.

Guidance for VA merit proposals requesting MVP data access and associated guidance is forthcoming.

ORD will be announcing a concept RFA for joint VA-Department of Energy (DOE) projects. This opportunity will be for clinically relevant scientific questions that require artificial intelligence (AI) and machine learning (ML) tools as well as intensive computing resources and data science expertise that are not available within the VA and are available at the Department of Energy. Copies of the VA CDW data and MVP data are housed at DOE's Oak Ridge National Laboratory. Concepts that are approved will pair VA investigators with DOE scientists to develop two-year projects that will be conducted at ORNL.

7. Service Funding Opportunities, Reviews and Updates

- Cross services announcements Wendy Tenhula, PhD

eRA updates

Updated [VA Application Guide SF 424 \(R&R\)](#) published on October 1, 2021. Changes are applicable for the Fall cycle (September application submission). Summary of Key Updates:

- Section 2.2 Funding Opportunities: Updated description for VA-ORD Research Career Development Award for Scientists Associated with Minority Serving Institutions (MSI-CDA) (IK2);
- Section 3.4 Other Project Information, #8. Director's Letter: additional content requirements;
- Section 3.5 Senior/Key Person Profile(s) Form: Updated other support policy to include resources and/or financial support from foreign entities.

ORD Post COVID-19 conditions RFA

In addition to ORD's parent RFAs, we are currently planning a collaborative funding opportunity based on the Collaborative Merit program of the Biomedical Laboratory and Clinical Science Research and Development Services. This opportunity will allow investigators to submit individual applications as part of a group of 3 projects that address

a common clinical or scientific issue relevant to post-COVID-19 conditions. These collaborations may be across research services or within one research service and will be supported by additional funds for core infrastructure. Applicants can propose up to three core infrastructure components (one being an administrative core) to advance data or methods, explore mediating or moderating risk-factors, develop new biomarkers for post-COVID-19 conditions, or improve engagement of clinical partners or patients, among others. We anticipate release of the RFA by November 7th. We are releasing this information now so individual investigators can consider and develop collaborations with other teams in order to move needed scientific evidence and knowledge forward. The initial stage of the application process will require a letter of intent (LOI) describing the clinical or research problem of interest, the aims and methods for each of the three studies, and the role of infrastructure cores. Investigators with approved LOIs will then develop full applications which will be reviewed by a single, cross-disciplinary panel. ORD will conduct a webinar in advance of the LOI deadline to answer questions. The anticipated deadline for LOIs is January. Please note: applications submitted to HSRD or RRD for the December 2021 deadlines may be included in a LOI for the collaborative funding opportunity.

- BLR&D Updates

Holly Krull, PhD

FY 2022 RFAs

A reminder that RFAs for FY2022 were released on October 4.

Fall Review Round

Proposals are currently being assigned to reviewers. The stations are reminded that they should not contact the Scientific Portfolio Managers about applications but should direct any questions to the Review Manager, Dr. Michael Burgio.

Spring submissions LOI deadline

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, 2021**. 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.

ORD Shared Equipment Evaluation Program (ShEEP) [IS1]

BLR&D will release an RFA to solicit applications for ShEEP funding. The new RFA will be posted this week (the week of Oct 18). Deadline for submission of application is December 8. Please direct any question to alex.chiu@va.gov

BLRD Eligibility program updates

Thanks to Dr. Alex Chiu who has been managing the program since the current process was established. Welcome to Dr. Mario Rinaudo who will be managing the program going forward. **The window for the submission of nomination packages will open on Nov 1, 2021 and close Dec 1, 2021 (No exceptions)**. The updated program guide is available on the BLRD Resources page, [GUIDANCE FOR REQUESTING ACCEPTANCE INTO THE BIOMEDICAL LABORATORY R&D \(BLRD\) PROGRAM FOR NON-CLINICIAN SCIENTISTS \(va.gov\)](#)

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 6, 2021**. Contact Dr. Arun Sharma (arun.sharma@va.gov) 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.

BLRD's Clinician Scientist Investigator (CSI) Award

The deadline for submitting a nomination package for consideration of a Clinician Scientist Investigator Award is **January 5, 2022**. BLRD would like to invite clinician scientists with a competing renewal of their BLRD Merit under review for the Fall 2021 cycle to consider applying for a Clinician Scientist Investigator (CSI) Award. The CSI Award will allow for a Merit award extension of up to 2 additional years (for a total of 6 years) and up to 4 additional years (for a total of 8 years) for a Senior Clinician Scientist Investigator (SCSI) Award. All nomination packages must be submitted to the VHABLRD-CSR@va.gov mailbox by the research office before **January 5, 2022**.

The nomination instructions can be found on the CSI website. A link will be included in the field conference notes.

CSI Website: <https://www.research.va.gov/services/blrd/csi.cfm>

Question about the CSI program contact: Kimberlee.potter@va.gov

2022 Middleton Award Nominations

The deadline for submitting a nomination package for the 2022 Middleton Award is **February 1, 2022**. The **Middleton award** is 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 mission.

All nomination packages must be submitted to the VHABLRD-CSR@va.gov mailbox by the research office before **February 1, 2022**.

The nomination instructions can be found on the Middleton website. A link will be included in the field conference notes.

Middleton Website: [William S. Middleton Award \(va.gov\)](#)

Questions about the Middleton Award contact: Kimberlee.potter@va.gov

Project Modification Requests

Because recently, some changes to projects that would require service director approved project modifications (PMOs) have been found in annual Research Project Progress Reports we wanted to remind the field of this requirement and the availability of a guidance document on the ORD website. Changes to research projects which have recently occurred without approved PMOs include research involving the addition of canines, felines or non-human primates, a foreign entity, human embryonic stem cells and NIDA pharmacy-controlled substances requiring ORD approval. Please, reinforce the importance of obtaining approved PMOs for these and other significant changes to funded projects.

- CSR&D Updates

Terri Gleason, PhD

New ORD Webpage on Suicide Prevention

[Suicide Prevention Research \(va.gov\)](#) now includes information on:

New Senior Portfolio Manager for Suicide Prevention Research, Dr. Joe Constans

New trials database on suicide prevention developed by co-leads Drs Laura Denneson and Maya O'Neil.

2022 Barnwell Award

Applications are due COB February 1, 2022. Nominations may come for the VA medical center, or CSR&D 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 if you have questions. His email is mark.roltsch@va.gov

The information is found on the ORD website just search Barnwell Award
The website is https://www.research.va.gov/services/csrd/research-awards.cfm?_ga=2.56572011.1990953416.1542631466-377307463.1536175624#barnwell

Letters of Intent

Due NOVEMBER 1 including CLINICAL TRIALS and Career Development

Specifically for Career Development:

The next BLR&D and CSR&D Career Development Letter of Intent (LOI) deadline is **Monday, November 1st, 2021.**

1. BLR&D and CSR&D Career Development LOIs are to be sent via email to VHACADEReview@VA.gov on or before November 1, 2021. Requests for extension of this deadline must be received PRIOR to the deadline, and require a memo to the service director from the Associate Chief of Staff for Research (ACOS/R) with justification describing an extenuating circumstance.
2. All submissions undergo an administrative review followed by a scientific review. Service directors will make the final determinations. Our goal is to have decision letters back to the field 30 days after the submission deadline.
3. All LOIs should be prepared in accordance with the policy/guidance documents available on our website, including the following references:

A. *ORD Career Development Program Web Page*
<https://www.research.va.gov/funding/cdp.cfm>

This page includes general information about the program that applies to all ORD funding services.

B. *Guidance for Submitting Career Development Letter of Intent (LOI) to BLR&D and CSR&D Services (Sep 2019)*
https://www.research.va.gov/services/shared_docs/GuidanceBLRD-CSRDCDA1-2-LOI.pdf

This guidance document includes specific instructions and requirements for CDA-1 and CDA-2 LOIs submitted to BLR&D and CSR&D.

The final page above is a checklist. **It is strongly encouraged that you utilize that checklist while preparing, finalizing, and submitting an LOI.**

- HSRD & QUERI Updates

David Atkins, MD, MPH

A program announcement was released on Friday 10/15 indicating the areas of interest for HSRD in the area of Post-COVID conditions. We will review individual PPO and IIR proposals for the December deadline. In addition, the announcement indicates a coming opportunity for people to submit a collection of 3 individual projects under a collaborative funding opportunity that would also support infrastructure to promote cross-project collaboration.

Funding decisions have been finalized for the Summer SMRB round and funding notices communicated to field on Monday evening. We were able to increase overall funding, increase # of CDA's and maintain a healthy funding line for IIRs and PPOs. A reminder that this fall will be the last opportunity to submit under our Service directed Research solicitations:

HX-22-023 HSR&D Targeted Solicitation for Service Directed Research on Social Determinants of Health.

HX-22-024 HSR&D Targeted Solicitation for Service Directed Research on Opioids Safety and Opioid Use Disorder.

Thereafter these applications will come in under our standing research solicitation.

- RR&D Updates

Patricia A. Dorn, PhD

Congratulation to Becky Gius, MA, James A Haley VA, Tampa, FL



Early Career Poster Awardee, *What Psychological and Sociodemographic Challenges are Linked to Criminal Justice Involvement among Veterans and Service Members with and without TBI? A LIMBIC-CENC Study*. Presented at American Congress of Rehabilitation Medicine, 2021 Annual Conference. VA/DoD LIMBIC-CENC is the consortium on chronic effects of neurotrauma (e.g., blast trauma).

Congratulations Dr. Ron Triolo, DAV's Department of Veterans Affairs, Veterans Health Administration Employee of the Year



Dr. Triolo, Director of the RR&D Advanced Platform Technology Center (APT) at the Louis Stokes Cleveland VA Medical Center and a Tenured Full Professor in the Department of Biomedical Engineering at Case Western Reserve University, was named Department of Veterans Affairs, Veterans Health Administration Employee of the Year by Disabled American Veterans for his work in restoring movement and sensation for Veterans with paralysis and limb loss. This award honors VA employees whose actions are exceptional examples of DAV's core values of Service, Quality, Integrity and Leadership. DAV's National Commander Stephen "Butch" Whitehead called Triolo a "pioneer" in developing technology that improves the lives of Veterans.

At the APT Center, Dr. Triolo manages and oversees research projects that help restore Veterans' abilities to move and feel after amputation or central nervous system compromise. Along with a primary focus on rehabilitation for Veterans living with spinal cord injury, stroke or multiple sclerosis, the APT Center also pursues cutting edge research into wireless health-monitoring systems to assess complications that stem from various muscular, skeletal, or neurological conditions.

RR&D Center Research Leads to NIH Collaborative Multicomponent Award (U19)



Congratulations to Dr. Sulayman Dib-Hajj, Deputy Director of the RR&D Center for the Restoration of Nervous System Function at West Haven VA, on his recent NIH U19 Cooperative Agreement Award, "Site-directed RNA editing of Nav1.7 as a novel analgesic". Dr. Dib-Hajj's U19 is based on research on sodium channel function following trauma and disease, supported by the Center's core funding. The project is a multi-PI, team-based approach including investigators from West Haven VA/Yale, University of Texas (Dr. Gregory Dussor), and Woods Hole Marine Biological Laboratory (Dr. Joshua Rosenthal). The project focuses on editing the mRNA of the sodium channel subtype 1.7

by converting one amino acid for another – in this case adenosine to inosine, making the channel permeable to both sodium and potassium ions attenuating neuronal firing and thus, decreasing pain. The U19 mechanism is milestone-driven and supports a research program of multiple projects directed toward a specific major objective, basic theme or program goal, requiring a broadly based, multidisciplinary and often long-term approach. This is a highly novel and innovative approach, and could result in 1 -2 lead non-opioid, biological candidates that would benefit Veterans and civilians living with chronic neuropathic painful conditions.

Review Updates:

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

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 – October 1, 2021
 - NOTE: An updated VA Application Guide SF 424 (R&R) was published 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

Notes Regarding eRA

- The NIH has announced a new eRA Commons login option. **All users will be required to switch by early 2022.** For details, see [Two-Factor Authentication: Accessing eRA Modules via login.gov](#).
- Update: Notification of Upcoming Change in Federal-wide Unique Entity Identifier Requirements [NOT-OD-21-170](#).

- All Senior/Key Personnel listed on the R&R Senior/Key Person Profile (Expanded) form on an application must enter a valid eRA Commons username (Commons ID) in the “Credential, e.g. agency login” field. **For application submission due dates on or after January 25, 2022, applicants will receive an error** that must be corrected in order to successfully submit the application. For details, see [NOT-OD-21-109](#).