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 2021 Annual Conferences**

NAVREF will be holding its annual conference that includes ACOS-Rs and AOs in a virtual and in-person format this year. The virtual portion will be on Aug 23-25 and ORD has purchased a limited number of licenses/seats for those who are unable to join through their respective VA affiliated non-profit corporation. ORD is currently working on managing the availabilities of these seats and will provide more info in the upcoming weeks if you have a need for one.

The in-person conference will be in New Orleans from Sept 12-15. Details on both meetings are included in the attachments.

- **ORD Centralized Clinical Research Services Contract**

ORD is in the process of setting up a centralized clinical research contract to help with future capacity needs on activities such as obtaining biospecimens, survey administration and other needs that may require additional support not often readily available. Info was sent previously regarding opportunities to participate in workgroups to help with the execution of the contract when awarded. If interested, please contact Grant Huang and Tony Laracuente.

- **ACOS-R Survey for Executive Leadership Training**

As part of efforts to provide professional development opportunities to ACOS-Rs, a survey will be issued in the upcoming weeks soliciting input into key areas of interest for a curriculum. ORD is partnering with the Employee Education Service to develop this program to help in areas beyond standard training offered in TMS. This is an executive leadership training for researchers within the federal government environment and not a
management training, regulatory training or HR initiative. It is not supplanting existing internal trainings. When ready, participation in this executive-level leadership training will be voluntary, and based on a desire to cultivate leadership skills and expertise. The survey is anonymous and information is intended only to help inform the development team on determining key areas of interest and need. ORD would like to have training contents that are relevant, meaningful and customized.

Appreciation was expressed to those ACOS-Rs who have already helped with some initial feedback on efforts.

- **Retirement – Director of Operations**

Dr. Marisue Cody’s upcoming retirement at the end of July was noted and appreciation was expressed for her 25 years of service. She has been a well-respected leader and mentor to many and will be greatly missed. However, ORD and the field communicated many well wishes for her next phase in life.

- **Chief Veterinary Medical Officer Updates**

  George W. Lathrop, Jr., DVM

  **Sensitive Species Research**

  Consistent with previous announcements from the CVMO, initiation of research protocols involving sensitive species require written approval from the VA Secretary. This requirement is mandated by law and restricts the use of VA funds without appropriate approval.

  Only those protocols listed on the CVMO/ORD website as currently active with these species should be acquiring new animals or be fostering continued work.

  The process for gaining this approval is in place with one protocol in the pipeline. It needs to be emphasized that this mandated, by law, restriction applies to studies conducted on VA property, using VA funds or conducted by VA personnel on VA duty.

  A gentle reminder via this forum will be generated every July for our report to Congress.

3. **Research Protections & Policy**

  Molly Klote, M.D., CIP

  **VAIRRS** – Now that all 104 medical centers with research programs have access to the platform, we are entering Phase 4 of the implementation which is the data integrity phase to ensure the enterprise dashboards have accurate data. There is a communication that recently went out from the VAIRRS program describing the initiative to have investigators complete the “wizard” coversheets (project and IRB (if applicable)) in the system. It is from the wizards that the dashboards draw some of their information. We would appreciate your support in encouraging investigators to complete their system wizards. Other dashboard information comes from the system processing data itself.
A continuing education module from IRBNet was recently negotiated, so if your facility could benefit from additional training, please reach out to the VAIRRS team at: VAIRRS@va.gov

OGC just signed off on the use of IRBNet for financial conflict of interest processing. The contract modification for the new module is expected to be approved before the end of this FY, and education and training will begin in early October (sooner if we are able).

ORD communications will be launching its move onto the IRBNet platform in the near future for submissions of publications/presentation/abstracts related to research projects.

Research ISSO and privacy reviews are now expected to be performed in the IRBNet system.

CTMS – We are in the market research phase of the acquisition plan for the Clinical trials Management System and over 18 researchers and other research staff who will need to interact with the chosen system, are helping to test the functionality in sandboxes with synthetic data. We owe these testers a debt of gratitude as it is a lot of work to test and report out on the 6 systems that were able to meet the security requirements. Saiju Pyarajan, Polly Dhond, and Angie Foster are doing an amazing job in coordinating this effort!

EHRM - The change to the Cerner EHRM (Millennium) will have a significant impact on research. From billing to data integrity, there is much to learn. Communication is tricky as the roll out is very protracted. Giving detailed information to sites who are years away from implementation will ultimately result in news fatigue, but making sure that you all know that there are teams working on the many issues related to research is the main message today. Multi-site studies involving transitioned sites and studies that acquire new data from transitioned sites will be the first remotely impacted. We are away and working on these issues. Maria Souden and her team are the leads for the EHRM work and are working hard for all. Dr Matthews, VHA, is setting up an internal VHA EHRM support structure and we believe that research will play a larger role in data governance and processes.

Proactive Calling for research recruitment – Since 2006 there has been a prohibition on “cold calling” Veterans to join research studies due to a data breach and the fear that scammers would harass our Veterans. COVID revealed that there are times when time is of the essence to contact a Veteran and have him/her be invited to join a research study. Dr Stone signed off on allowing ORD to establish a framework and central approval process to reach out to Veterans by phone. ORD is working on the roll out plans at this time. This will be very limited in its use. More to follow by mid-August. Please do not reach out to my office (or any of my staff) for additional information at this time.
4. **Finance Updates**

Mr. Verwiel reminded the field that Prior year funds need to be executed by August 1st, 2021. PY unobligated balances were $16M last week. Thank you to the highest 13 stations that provided execution plans on how to execute their PY funds. Current year Expenditure report was completed for 99.7% of all projects. Thank you to all Stations for timely reporting of their expenditures by project. American Rescue Plan (ARP) funds will be sent out for $9M to the top 10 stations. The Expenditure report just completed will be used to help determine which stations will receive these funds. FY22/23 budget of $882 was a $67M increase from CY. Congressional mark was $20M higher than the Presidential budget. A potential budget of $902M for FY22/23. The Initial Distribution plan was approved and briefed to the Directors last week.

5. **ePROMISE**

**Clinician Status**

Several years ago, ORD added a field named Clinician Status to the Investigator profile. Because there were so many investigators in the system, ORD had Yes, No and N/A. The intent was to identify each active investigator as a clinician or a non-clinician with clinician being identified as a *licensed practitioner who is participating in patient care activities at a VA Medical Center.*

This data has become critical as we are looking to answer several questions regarding project funding tied to clinicians, how many clinicians are funded etc., etc. When we pulled the data we found that we had a large number of active investigators listed as N/A. I sent an email out on July 1 asking you to review and update. We have cut that number by 1/3 so thank you. In the next few days we will send out an updated listing of investigators who need that field updated. We can make a large dent if the top 10 facilities on the list take a few minutes and update the status by going to the investigator profile and updating the field and saving.

Thank you in advance. We hope to have the remaining 450 or so corrected soon. Questions regarding this or any field operations issues can be directed to me.

6. **GAO NRAC Subcommittee update**

Slides are provided as an attachment to these notes. Dr. Schulteis highlighted best practices for improving research relationships with academic affiliates and VA affiliated non-profit corporations. These areas focused on: communication; establishing a larger picture of the partnership; developing people (especially leadership roles); efforts for develop the NPC as a partner; ORD efforts to disseminate and clarify key policies; and having written documents in place. Dr. Huang highlighted how the ACOS-R training referenced earlier may help with the leadership development recommendation.
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

**Review Updates**

*Spring Review Round:* The margin meeting for the Spring round was completed last week so investigators are free to schedule time with their review managers to discuss their proposals.

*Fall Review Round:* Submissions for the fall round open on August 3rd. RFA updates will be posted prior to that date.

**Clinician Scientist Award Extension Program:**

Investigators with Clinician Scientist Award Extensions should be aware that extension requests are subject to administrative review to confirm that adequate progress has been made on the original aims, that productivity levels have been maintained and that new aims and experiments are described for the period of the extension. Any negative impact of COVID-19 on research productivity should be described. Local stations should work with their CSIs to ensure that adequate documentation is submitted.
Recognition:

RR&D congratulates Rosemarie Cooper, MPT, ATP Associate Director for Stakeholder Engagement at the RR&D Center for Wheelchairs and Assistive Robotics Engineering at the VA Pittsburgh Healthcare System. She is the recipient of the 2021 Paralyzed Veterans of America Clinical Excellence Award in Therapy. This award, presented annually, recognizes a clinician who has achieved national recognition in the provision of exceptional professional achievement, exemplary treatment, strong leadership and personal advocacy to improve the lives of individuals living with spinal cord injury or disease, amyotrophic lateral sclerosis, or multiple sclerosis.

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.

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 – 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.

Under Secretary for Health Award

Dr. Donna Washington, Director of the VA Office of Health Equity/QUERI Partnered evaluation Initiative, Professor of Medicine at the UCLA Geffen School of Medicine and staff physician at the Greater Los Angeles VA Healthcare System, is the recipient of this year’s Under-Secretary’s Award for Outstanding Achievement Award in Health Services Research. She was selected among seven highly accomplished nominees to receive this award. Dr. Washington is an extraordinary, nationally recognized VA health services research scientist, devoted mentor and a proven administrative leaders, whose work has had and continues to have an outstanding impact on VHA, particularly in the areas of women’s health and diversity, equity and inclusion.

HR Updates

We have selected a new SPM for the Aging LTSS portfolio (vice George Fitzelle’s position) and an SPM for the Informatics/virtual care position (vice Miho Tanaka). We anticipate that their tentative start dates will be in mid-August.
Recruitment is still ongoing for a third SPM (vice Nsini Umoh’s position) to oversee the Equity/Women’s Health/Rural Health portfolios.

Diversity, Equity and Inclusion Updates

Four HSRD projects were among the 10 awarded Diversity Equity and Inclusion supplements by ORD. Congratulations to all of our HSR&D awardees for this wonderful DEI award.
SMRB Update- Summer 2021 Cycle

- HSR&D’s Scientific Merit Review Board and Career Development Award review meetings are both scheduled to take place virtually August 24 - 27, 2021.
- HSR&D received 29 CDAs, 28 Pilots, and 112 IIRs, for a total of 169 applications.
- For questions regarding the review process, please contact Scientific Merit Review Program staff at vhacoscirev@va.gov

CIDER Updates

ESP Reports:

- Evidence Brief - Coronary Computed Tomography Angiography with Fractional Flow Reserve in Noninvasive Diagnosis of Coronary Artery Disease
- Evidence Inventory - VA vs Non-VA Quality of Care

Impacts:

- Improving the Safe Use of Direct Oral Anticoagulants for Veterans
- Diffusion of Excellence Shark Tank Winner Impacts Lung Screening Guidelines
- Partnered Evaluation Advances Whole Health System of Care across VA
- Study Leads to New Cost-Effective Benefits for Women Veterans Taking Oral Contraceptives

CDA Updates

- IRBnet is now live for GS14/15 field promotion nominations! If you did not get a chance to attend the Webinar last Wednesday (6/23) week, Copies of the new instructions, FAQs and the June 23 webinar recording have been posted to the centralized positions website- https://www.research.va.gov/resources/centralized_positions.cfm.
- HSR&D will no longer be accepting promotion packets by email. The next deadline for promotion nominations is September 1.
- Palo Alto will be hosting a virtual CDA Conference September 22-24 (10a.m – 1 p.m. each day Pacific Time). Meeting planning has begun; please save ask awardees to save the date.
- 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. 29 and 13 proposals were received this round for CDA and HSR6 respectively.
- 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.
Review Updates

Spring 2021 round of review. - CSRD just finished finalizing funding decisions from the Spring 2021 round of review. Congratulations were extended to the entire group of investigators who submitted very competitive applications. CSRD thanked all of their scientific peer reviewers (VA and non-VA) for their critical contribution to this process. And CSRD is grateful to all of their Scientific Portfolio Managers for the hours they put into making sure the slate of to be funded applications was in good shape.

While the intent to fund notices, etc., will proceed, CSRD noted that the one thing that they hoped everyone will quickly pay attention to is the associated list of requirements for each funded program as specified in our Just in Time (JIT) system. This is the very first step in successfully launching studies and effective budget management – resolving JIT elements, and starting projects as soon as possible.

CSRD also introduced their new Scientific Portfolio Manager, Dr. Nick Simon, who started on board 7/19/21. Nick will be serving BL and CS as portfolio manager for some of oncology, and we hope everyone will extend him a warm welcome: Nicholas.simon@va.gov

Award

CSR&D is pleased to welcome our first Awardee for the Office of Research and Development (ORD) Research Supplements to Promote Diversity, Nadir Balba, PhD from the Portland, OR VA Medical Center. These competitively reviewed awards are intended to provide supplemental funds to a VA Merit in order to offer a mentored research experience to an early career scientist from an underrepresented background as they prepare for a VA Career Development Award application. Dr. Balba will be working with his funded VA mentor, Dr. Miranda Lim, (PI of: CX-002022-02, “Supplementation with Amino Acid Rehabilitative Therapy in TBI (SmART-TBI): A Randomized Placebo-Controlled Trial to Improve Sleep”), to pilot an internet-delivered mindfulness intervention for Veterans with TBI/PTSD. Many congratulations to Drs. Balba and Lim as they pursue this highly significant research for our Veterans.

Career Development Symposium

Lastly, the CSRD annual Career Development Symposium for awardees is being organized. This meeting will plan to convene virtually again this year with the first and third year awardees across BL and CS. Monday, September 13 and Tuesday, September 14 for the bulk of the meeting, with Thursday, September 16 as the day for SPMs to meet with awardees in their portfolio. This is the same format as the 2020 meeting. This symposium is typically a rich and valued experience for awardees, and we hope all of the local offices will help facilitate their awardees’ participation in any way they can.

POC’s: Eric.schwinder@va.gov and Mark.Roltsch@va.gov