|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |

|  |  |  |
| --- | --- | --- |
|

|  |  |
| --- | --- |
|

|  |
| --- |
|  |

 |

 |

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|

|  |  |  |  |
| --- | --- | --- | --- |
|

|  |  |  |
| --- | --- | --- |
|  |  |  Clinical ScienceResearch and Development |

 |

 |

|  |  |
| --- | --- |
|

|  |
| --- |
|  |

 |

 |

 |

 |

|  |  |  |  |
| --- | --- | --- | --- |
|

|  |  |  |
| --- | --- | --- |
|

|  |  |
| --- | --- |
|

|  |
| --- |
| ****Terri Talks******Vol. 3, No. 5, 2021.5.27** |

 |

 |

 |

|  |  |  |  |
| --- | --- | --- | --- |
|

|  |  |  |
| --- | --- | --- |
|

|  |  |
| --- | --- |
|

|  |
| --- |
| Message from the DirectorThis month’s reflection is on collaboration. While we say we are stronger together, we do want to continue to emphasize the importance of working together beyond a singular laboratory, or facility, or VISN. An enterprise-wide approach has been particularly strong related to research on COVID-19. One example has been the Community of Science webinars and resulting scientific collaborations. However, I wanted to emphasize the importance of this consideration in CSRD research going forward – as we will especially look to support collaborative efforts on important topics that present potential unique advances. So, how to present a collaborative activity? There are multiple ways in which CSRD will support investigators’ collaborative activities. Examples include focused meetings of working groups, service-directed research especially for high priority topics, and through the collaborative merit program. The collaborative merit program offers linked merit reviews and includes coordination support as well.  The first stop is to connect with other researchers to develop proposed collaborations. The next step would be to review your collaborative proposals by vetting them with your scientific program officers.  Several exciting ongoing and recent collaborations include a working group focused on medicinal cannabis that had a multi-site trial funded as a result of its efforts, an expert group considering ketamine research priorities – funded for major depressive disorder, and also a group was funded to explore the benefits of stellate ganglion block for PTSD. Please do let us know about collaborative activities we should consider together. Thank you all as always, Terri |

 |

 |

 |

|  |  |  |  |
| --- | --- | --- | --- |
|

|  |  |  |
| --- | --- | --- |
|

|  |  |
| --- | --- |
|

|  |
| --- |
| LOIs Received for Spring Funding RoundCSRD has a requirement for a Letter of Intent (LOI) to be approved prior to submitting an application that is for the Career Development Program or a clinical trial. The deadline (May 1, 2021) resulted in 29 LOIs for Clinical Trials. Career Development Program Letters of Intent received totaled 40, including 18 for BLRD and 22 for CSR&D. We use the opportunity in LOI review to ensure the service direction, eligibility, and proposed science are aligned with CSRD interest and priorities. We intend to send response letters to submitting research offices no later than June 1. We also encourage applicants to read the letter for important feedback, including the encouragement to contact their specific program officer in advance of application submission.Update on SupplementsIn response to CSRD opportunity for research supplements, we approved, for both partially and totally approved requests, **$2.5 million.** Decisions by CSRD leadership were sent to research offices by May 21, 2021. This opportunity for supplemental funds was the result of return of funds and reset of end dates due to the extent to which clinical research was adversely affected by the pandemic. Requests were submitted to cover ways that CSRD researchers might work to catch up on delays due to the pandemic, and we hope that the funding will indeed help investigators strengthen their results.Single IRB Exception has new Application ProcessOf note for CSRD multi-site studies:  A new process for submitting Single IRB Exception applications is in place via a SharePoint portal as of May 1. The previous application process utilized email. VA non-exempt human subjects research approved or transitioned to follow the 2018 requirements of the Common Rule is required to use a single IRB if more than one institution is engaged in the research unless either (a) single IRB review is required by law, such as tribal law; or (b) any Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context. ORD has a process to evaluate requests for Single IRB Exception for VA Facilities participating in these studies, regardless of whether it is unfunded or funded by VA or another Federal Agency. Requests for Single IRB Exception must be submitted to: [ORD Single IRB Exception Requests - Home (sharepoint.com)](https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fdvagov.sharepoint.com%2Fsites%2FVHAORPPE%2FIRBRelianceRequests%2FHome&data=04%7C01%7C%7C0fe0e9ef76b14a6020a708d9214fe5d6%7Ce95f1b23abaf45ee821db7ab251ab3bf%7C0%7C0%7C637577449297190625%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C1000&sdata=pJqsI%2F8yYnauMKvNES9C4FRYPvWxQ8ukCkSefxSe3wQ%3D&reserved=0) Only users with a va.gov email address can access the SharePoint site, and ORD policy only allows the single IRB exception request form to be submitted by the ORD funding service, ACOS/R&D, AO/R&D, VA Human Research Protections Administrator, or VA Facility’s IRB Administrator. Investigators are not permitted to request the Single IRB Exception.  For additional information, a PowerPoint presentation from a recent webinar provided by the Office of Research Protections, Policy and Education (ORPP&E) is available at [https://www.research.va.gov/programs/orppe/education/webinars/orppe-042921.cfm](https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.research.va.gov%2Fprograms%2Forppe%2Feducation%2Fwebinars%2Forppe-042921.cfm&data=04%7C01%7C%7C0fe0e9ef76b14a6020a708d9214fe5d6%7Ce95f1b23abaf45ee821db7ab251ab3bf%7C0%7C0%7C637577449297200582%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C1000&sdata=FE4Wyi9VPzutBiSGh25KsaKMXhTMD1pm%2FJIoZceLY5A%3D&reserved=0). The PowerPoint presentation includes instructions for the submission process. Questions about the process may be submitted to IRBRelianceandSIRBExceptions@va.gov.Research Supplements to Support Diversity due June 1Eligible PIs with VA Merits with at least 2 years remaining may apply for this supplement that supports mentored research experiences for early career scientists from underrepresented populations. Other criteria for applicants include underrepresented racial and ethnic groups, individual with disabilities and Veterans. For information or to receive a copy of the announcement, email Carol.Fowler@va.gov.Please Meet and Greet UsUntil we are able to travel, CSRD staff members will be attending virtual meetings:* **44th Annual Meeting of the Research Society on Alcoholism, June 19-23.** A VA Data Blitz Workshop is being organized with Dr. Robert Swift, Associate Chief of Staff for Research at the Providence VA Medical Center.  Dr. Jana Drgonova, Scientific Program Manager in CSRD, will present funding opportunities at the VA. Scientists from her portfolio and Rehabilitation Research and Development will showcase what is possible with VA support.

DMC Members NeededCSRD's Centralized Data Monitoring Committee is currently seeking members for two panels – Medical/Surgical (M/S) and Psychiatric, Behavioral Health and Neurologic Disorders (PBN). Qualifications for membership include funding history and clinical trial experience, academic position of associate professor or above, a solid publications record, and review experience. Immediate needs are for cardiologists and biostatisticians. Pulmonologists, oncologists, urologists, and neurologists also are needed. For more information, please contact  Dr. Tamara Paine (Tamara.Paine@va.gov).CSRD Contact InformationGeneral Mailbox: VHABLRD-CSRD@va.govJust in Time: [https://vaww.gateway.research.va.gov/jit/Default.asp](https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fvaww.gateway.research.va.gov%2Fjit%2FDefault.asp&data=04%7C01%7C%7C0fe0e9ef76b14a6020a708d9214fe5d6%7Ce95f1b23abaf45ee821db7ab251ab3bf%7C0%7C0%7C637577449297200582%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C1000&sdata=SnOp5FX6%2BJEQ%2Bb3bF1WSE4pHQ3BzAB5Dxq3aHOvbZfk%3D&reserved=0)?Career Development: VHACADEReview@va.govClinical Trials: clin-review@va.gov |

 |

 |

 |

 |