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| |  |  |  | | --- | --- | --- | | |  |  | | --- | --- | | |  | | --- | | Message from the Director We have received much expressed interest from stakeholders, including Congress, on particular interventions that have anecdotal stories of effectiveness, yet are not supported by scientific evidence. We are interested in supporting research for treatment solutions and developing the evidence base including understanding benefits and risk. When the drumbeat grows for a certain intervention, however, it becomes very important for us to strategically plan how to logically address. In these cases, we work to develop a strategy for making funding decisions in priority order and in some cases using roadmaps, which we will continue to disseminate.  Some of the “hot topic” interventions about which we need to be very strategic include ketamine and esketamine, psychedelic drugs, and medical marijuana, to name a few very common queries.  If there is interest about any of these “hot topic” interventions, we ask applicants to reach out to us in advance of expending effort on applications (including Letters of Intent). The overall idea is if we are organized strategically, then scientists will be able to make better decisions about how to expend efforts while we work together towards scientifically sound treatment solutions for Veterans.  Please do connect early if you are thinking about such work going forward.   –Terri | | | |

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We understand the specific challenges to clinical research due to the pandemic; however, as of June 21, 2021, we have stopped accepting returns and ask research offices to continue to try their best to obligate funds on station this fiscal year. Letter of Intent Results Reported Results of our reviews of Letters of Intent (LOIs) for both Career Development and Clinical Trial applications considered in advance of the Fall 2021 round submission appear below.  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 in 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 Scientific Portfolio managers 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 Career Development LOIs** | | **CSRD Clinical Trials LOIs** | | | Received | 25 | Received | 29 | | Approved | 17 (77%) | Approved | 19 (65.52%) | | Disapproved | 4 | Disapproved (Other Service) | 3 | | To Other Service | 0 | Disapproved (Standard Merit) | 1 | | Withdrawn | 1 | Disapproved | 6 |  COVID-19 Clinical Trials Update Provided This is an update 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.   |  | | --- | | CSRD Staff Highlight:Miriam J. Smyth Miriam J. Smyth, Ph.D., is the Deputy Director of the Clinical Science Research and Development Service (CSRD). Miriam joined the VA in 1995 as a researcher with the Durham Geriatric Research, Education and Clinical Center, while a faculty member at Duke University Medical Center. In 1999, she moved to the Baltimore VA and accepted a faculty appointment at University of Maryland Baltimore, School of Medicine. While at Baltimore, she conducted research in prostate cancer and was one of the two local site PIs for the Million Veteran Program. In 2006, she transitioned to research administration in the Research and Development Service at Baltimore, ultimately becoming Deputy Associate Chief of Staff for Research and Development. In 2015 she joined CRSD as Strategic Planning Manager and became Deputy Director in 2018 – a role she thoroughly enjoys.  **Fun fact about Miriam:** early in her career, she was a marine biologist conducting research on the reefs around Guam and St. Croix (U.S. Virgin Islands). In St. Croix, she worked on undersea research projects involving the Hydrolab - NOAA’s underwater research lab/habitat that housed four people at a time for periods of up to 14 days, allowing excursion dives to depths of more than 100 feet. In 1986, the habitat was moved to the National Museum of Natural History and was displayed in the museum's Sea Life Hall. While marine research is fun, research on land is safer! |  DMC Members Needed CSRD'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 **f**unding 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](mailto:Tamara.Paine@va.gov)). CSRD Contact Information General Mailbox: [VHABLRD-CSRD@va.gov](mailto:VHABLRD-CSRD@va.gov)  Just 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%7C56c453a5439c4e8ba3bc08d937f2345f%7Ce95f1b23abaf45ee821db7ab251ab3bf%7C0%7C0%7C637602335674922488%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C1000&sdata=jyYUcV2FEKtqcf1GaAFV97EZnybYMWyPZbcrfkw%2BVxw%3D&reserved=0)?  Career Development: [VHACADEReview@va.gov](mailto:VHACADEReview@va.gov)  Clinical Trials: [clin-review@va.gov](mailto:clin-review@va.gov)  Newsletter: [Lucindia.Shouse@va.gov](mailto:Lucindia.Shouse@va.gov) | | | |