

VISN 5 MIRECC PILOT STUDY PROGRAM

The MIRECC pilot research program invites study applications that support its mission of improving the care of Veterans with schizophrenia and other serious mental illnesses within the VISN, and ultimately, within the entire VA system and in the community at large. Projects dealing with other populations will occasionally be considered if the results promise to be applicable to our core mission. This program provides investigators with the opportunity to collect pilot data and test the feasibility of research ideas that can lead to larger externally funded NIH or VA grants. Proposals are subjected to peer review and must meet rigorous scientific standards. Additionally, proposals must satisfactorily meet standards of protecting human subjects.

SUBMISSION REQUIREMENTS AND REVIEW PROCESS

Eligibility Criteria – VISN 5 MIRECC Core and Affiliate Investigators are eligible to apply for pilot studies. Core investigators are researchers who receive salary support from the VISN 5 MIRECC. Affiliate investigators are researchers who have a VA appointment but do not receive salary support from the VISN 5 MIRECC (this includes individuals holding a Without Compensation [WOC] appointment). Junior Investigators (medical students, interns, residents, and fellows) are eligible to submit applications for pilot studies, but must identify a senior mentor (a MIRECC Core or Affiliate Investigator).

Award amount – Maximum award is \$25,000. If the pilot funds are to be transferred outside of the VA Maryland Health Care System (e.g to the Washington D.C. VA), the award will be distributed in quarterly installments. Satisfactory progress must be made on the pilot in order to receive subsequent installments.

Budget – Funds for investigator salary, travel, tuition, or IT equipment are not authorized. Funds for salary support for research assistants may be requested but requires careful planning beforehand. If you expect to require salary support for research staff, contact Dr. Fischer (contact information below) prior to submission to discuss details.

Timeline for Study Completion – Pilot studies should be completed in approximately one year. Projects encountering lengthy delays are expected to submit regular reports and may have funding put on hold until the delays are resolved.

Submission Process – Pilot study application deadline is **15 January**. Proposals will be peer reviewed for scientific merit, for compliance with administrative guidance, and for recruitment and staffing needs. Any concerns arising from this review process will be communicated to the project PI. If the problem is correctable, the PI will be allowed to address reviewer concerns and the proposal will continue to move through the award evaluation process. Depending on availability of funds, it is expected that approximately 4 projects will be funded per year. If there are more submissions than are fundable, the top grants will be funded based on scientific review and consistency with the mission of the VISN 5 MIRECC and its pilot grant program.

Final award decisions will be communicated on **01 March**. PIs will then have to submit “just-in-time” information prior to **30 September**. Funding will begin **01 October**.

Initial Application – The pilot study application should include: (1) MIRECC Pilot Study Application face page, (2) a short abstract (60 words or less), (3) the grant narrative, (4) citations, and (5) an itemized budget with justification. The grant narrative should be no longer than 4 pages exclusive of references. The grant narrative should include the following sections:

1. Specific Aims (suggested 1/2 page) – State concisely and realistically what the research is intended to accomplish. Indicate how the research relates to the overall mission of the VISN 5 MIRECC.
2. Background and Significance (suggested 1 page) – Briefly sketch the scientific literature pertinent to the proposed pilot study (and future grant application) critically evaluating existing knowledge and identifying the gaps that the pilot study are intended to fill.
3. Methods (suggested 2 pages) – Briefly describe the study design and the procedures to be used to accomplish the specific aims of the project. Include the means by which the data will be collected, analyzed, and interpreted. State where data will be stored. Provide detailed plans for recruitment of Veterans (i.e. which population the study will enroll, from which clinics, how will you advertise, how will you solicit referrals and communicate with providers).
4. Research Team, Timeline, and Future Plans (suggested 1/2 page) – Briefly describe the qualifications and roles of the research team. Include a timeline for the work planned, including a projected completion date. Describe any new instruments, tools, or materials that will be generated. Describe plans for how the proposed pilot study will support a grant application to the VA, NIH, or other federal funding agency.

Review Process and Criteria - Pilot study applications will be anonymously reviewed for scientific merit. Any concerns will be communicated through Dr. Fischer to the PI. After scientific review, administrative review will be done by the VISN 5 MIRECC Director, Dr. Richard Goldberg, and Research Core Associate Director, Dr. Julie Kreyenbuhl. Other reviewers will include Ms. Julia Evely, Director of Research Quality Management, and Mr. Steve Day, Administrative Officer.

Response to Review – Response to scientific review usually takes the form of a submitted letter listing the reviewer's critiques and how/if the protocol will be amended to address those critiques. The letter is submitted to Dr. Fischer who then examines the response with the reviewer. This process continues until the reviewer is satisfied all critiques have been adequately addressed or the study is deemed inappropriate by the reviewer. Administrative review is not blinded and responses are communicated directly with the reviewer (usually via email).

“Just-in-Time” Information – If the pilot is selected for funding, the following JIT information is required:

1. Names of all investigators and staff working on the project who will have contact with Veterans must be submitted to Ms. Norma Wharton and cc'd to Dr. Fischer and Mr. Steve Day to ensure they have proper VA training, scopes of practice, and other required documentation on file.
2. The PI should consider whether it would be useful to consult the Veteran's Advisory Panel. This panel can help plan study activities and recruitment from a Veteran's point-of-view. Contact Ralf Schneider to discuss further.
3. The PI must let Dr. Deb Medoff know whether the MIRECC data management infrastructure- including teleforms and data entry- will be required. Teleforms take advance notice to prepare and it is advised to contact Dr. Medoff early in the pilot grant process for discussion of needs.
4. All pilot studies are required to obtain MIRECC approval before commencing recruitment. This MIRECC review is SEPARATE from the review of the pilot application. For studies being conducted at the VAMHCS (using the University of Maryland IRB as the IRB of record), this entails entering the protocol into CICERO and giving Ms. Julia Evely access to it (preferred) or by sending her a pdf of the protocol. In D.C. or Martinsburg, this requires sending a pdf of what will be submitted to the IRB of record, *prior to submission*, for MIRECC review. The protocol will be evaluated for compliance with VA regulations and recruitment strategy. (Please see the attached VISN 5 MIRECC Recruitment SOP addendum for study requirements.) You must submit documentation that the MIRECC review of the protocol is completed and the study has received full MIRECC approval.

Once the JIT information is submitted, the pilot funds will be dispersed/accessible to investigators.

Year 2 Continuation Procedures –

As long as there are remaining pilot funds and no additional resources have been spent, a no-cost extension for projects may be requested. A progress report must accompany these requests.

If additional funds are requested in order to continue a project, a progress report must be submitted along with an accounting of the expenditures from the previous year and a new budget. These requests for a second year of pilot projects will be competing against newly submitted projects and no selective advantage will be given for continuation projects.

Reports –

Quarterly reports detailing progress and/or delays are due each quarter: 15 January, May, August. (See attached addendum for suggested report format.)

Final reports are due 3 months after the project ends (15 December). If a project is delayed, an annual report is due on the anniversary of the start date (15 October).

Contacts –

Interested applicants should contact Bernie Fischer, MIRECC Pilot Program Coordinator, at bfischer@mprc.umaryland.edu for more information on initiating the submission process.

Steve.Day2@va.gov

Steve Day
MIRECC Administrative Officer

Norma.Wharton2@va.gov

Norma Wharton

Julia.Evelly@va.gov

Julia Evely
Director, Research Quality Management, VISN 5 MIRECC

Ralf.Schneider@va.gov

Ralf Schneider
Coordinator, Veterans Advisory Panel

dmedoff@psych.umaryland.edu

Deborah Medoff, Ph.D.
Director, Data Management Core, VISN 5 MIRECC

jkreyenb@psych.umaryland.edu

Julie Kreyenbuhl, PharmD., Ph.D.
Associate Director, Research Core, VISN5 MIRECC

Richard.Goldberg@va.gov

Richard Goldberg, Ph.D.
Director, VISN 5 MIRECC