

October 1, 2024

Dear Colleague:

The VISN 4 Network invites you to submit an application for grant support from the Mental Illness Research Education and Clinical Center (MIRECC) Pilot Project Fund. The MIRECC is a VA Central Office (VACO) funded Center within the VISN designed to advance the health and care of patients with mental illness through the study and implementation of *precision mental health care*. Within the broad concept of precision mental health care, our MIRECC specifically focuses on the following aspects: the validation and incorporation of biomarkers, the incorporation of patient preference in treatment decision making, the development of tools to implement precision mental health care, and the development of treatment algorithms and decision aids. The purpose of the MIRECC Pilot Project Fund is to promote research that contributes to the Center's focus and potentially sets the stage for subsequent research funded through other VA and extramural sources. Clinical, research and educational proposals related to these topics are eligible for support.

A total of \$100,000 will be available during FY 2025, pending approval, to support pilot research projects by investigators interested in the study of disorders appropriate to the funding center's mission. Pilot funding will be made available to encourage the research careers of junior scientists, to enable senior scientists to pursue novel lines of scientific inquiry, and to enable senior scientists to test promising new methods or techniques. The highest priority for funding is for proposals that support new, unfunded investigators for projects conducted at the VA, particularly projects directed by MIRECC fellows. A second priority group for funding is junior investigators outside the MIRECC. Consideration will also be given to novel and innovative pilot work at the VA by established investigators within the VA or its affiliates who are not currently affiliated with the MIRECC or not currently conducting research on precision mental health care. To ensure the targeting of funding to the high priority categories of investigators and projects, it is anticipated that, in most cases, proposals reviewed in the first half of the year will be those from MIRECC fellows. *Investigators who receive MIRECC Pilot Project Funding and are not currently VA-affiliated, will need to become, at minimum, a without compensation (WOC) VA employee and fulfill all local VA Research Office requirements prior to funds being awarded.*

The type of research and the methods used are not limited and can range from basic science to clinical trials and health services research provided the project fits within the precision mental health care

theme of the MIRECC as described above. Emphasis is placed on the scientific merit of the research, the overall value of the project to the scientific mission of the MIRECC, and the potential impact on the health and well-being of Veterans. An important criterion used to evaluate proposals is their potential to yield data for use in obtaining research support through VA and other sources. To that end, junior investigators are expected to work with a mentor who has successfully obtained extramural grant funding [e.g., VA Merit Award applications, VA career development applications, NIH career development (K) awards, individual NIH research project (e.g., R01) applications].

Due to the large number of potential submissions, only one application per individual will be accepted during FY 2025. However, in some instances, revised submissions of previously reviewed applications will be considered. The amount of the MIRECC award is a maximum of \$25,000 per year. The total term of the award is one year. A six-month progress report and a final report when the project is complete are required. Expenditures will be audited by MIRECC Administration to ensure that expenditures are consistent with the approved proposals.

Letters of Intent (LOI) and full proposals are accepted on a monthly basis throughout FY 2025. The due date for each is the last Friday of the month (e.g., 10/25/24, 11/29/24). An LOI must be submitted and approved by the MIRECC Research Review Committee prior to the submission of a full proposal. Following approval of the LOI, the full proposal may be submitted at the next application deadline.

Applications should be emailed no later than noon on the last Friday of the month. Applications received after this time will be considered as a submission for the subsequent month. Incomplete applications, or applications not prepared in accordance with the instructions, will not be considered and will be returned to the applicant.

Any questions relating to the application submission should be directed to Sara Chapman, MS, OTR/L, Associate Director for Education, MIRECC, VA Pittsburgh Healthcare System (<u>sara.chapman@va.gov</u>). Any further questions regarding the MIRECC research mission can be directed to the MIRECC Co-Associate Director for Research, Dr. Henry Kranzler (<u>kranzler@pennmedicine.upenn.edu</u>) at the Corporal Michael J. Crescenz VAMC in Philadelphia or the Co-Associate Director for Research, Dr. Vishwajit Nimgaonkar (<u>vishwajit.nimgaonkar@va.gov</u>) at the VA Pittsburgh Healthcare System.

We look forward to your participation in this program.

Sincerely,

Henry R. Kranzler, MD Co-Associate Director for Research VISN 4 MIRECC Vishwajit Nimgaonkar, MD Co-Associate Director for Research VISN 4 MIRECC

Guidelines for the Submission and Review of Applications

OVERVIEW

The VISN 4 Mental Illness Research, Education and Clinical Center (MIRECC) invites proposals for pilot projects on new and innovative research on *precision mental health care*. Within the broad concept of precision mental health care, our MIRECC specifically focuses on the following aspects: the validation and incorporation of biomarkers, the incorporation of patient preference in treatment decision making, the development of tools to implement precision mental health care, and the development of treatment algorithms and decision aids.

A total of \$100,000 will be available during FY 2025, pending approval, to support pilot research projects by investigators interested in the study of disorders appropriate to the funding center's mission. Pilot funding will be made available to encourage the research careers of junior scientists, to enable senior scientists to pursue novel lines of scientific inquiry, and to enable senior scientists to test promising new methods or techniques. The highest priority for funding is for proposals that support new, unfunded investigators for projects conducted at the VA, particularly projects directed by MIRECC fellows. A second priority group for funding is junior investigators outside the MIRECC. Consideration will also be given to novel and innovative pilot work at the VA by established investigators within the VA or its affiliates who are not currently affiliated with the MIRECC or not currently conducting research on precision mental health care. To ensure the targeting of funding to the high priority categories of investigators and projects, it is anticipated that, in most cases, proposals reviewed in the first half of the year will be those from MIRECC fellows. Types of research are unlimited in terms of methodology and can range from basic science to clinical trials and health services research. Emphasis is placed on the scientific merit of the research and the overall value of the project to the scientific mission of the MIRECC and the potential impact on the health and well-being of Veterans. It is anticipated that successful pilot projects will be developed into VA Merit Award applications, VA career development applications, and/or NIH career development (K) or individual NIH research project (e.g. R01) applications.

SCIENTIFIC MISSION

The VISN 4 MIRECC Pilot Project Fund is designed to promote research which contributes to the longterm aim of enhancing the health of individuals with mental illness through the study and implementation of precision mental health care.

REVIEW PROCEDURES

Proposals are reviewed by the MIRECC Research Review Committee to determine whether research content and direction meet the established criteria. The following criteria will be considered in evaluating the merit of a proposal:

- 1. Relevance to the scientific mission of the MIRECC
- 2. Soundness of scientific principles
- 3. Novelty of the scientific approach
- 4. Scientific merit
- 5. Likelihood of providing new and valuable insights into precision mental health care
- 6. Background and experience of the investigator(s) and mentor (where appropriate)
- 7. Adequacy of resources and environment to support the project
- 8. Appropriateness of the budget for the proposed work
- 9. Potential to result in future VA or other extramural funding

BUDGET

Budgets of up to \$25,000 will be considered. MIRECC funds are not available for physical plant infrastructure and no indirect costs should be included in the proposed budget. There is no allowance for travel, tuition, publication costs or major equipment. A justification is required for all equipment items that exceed \$500 in cost.

GUIDELINES FOR LETTER OF INTENT (LOI) AND PROPOSAL PREPARATION

Letters of Intent (LOI) and full proposals are accepted on a monthly basis throughout. The due date for both is the last Friday of the month (e.g., 10/25/24, 11/29/24). *An LOI must be submitted and approved by the MIRECC Research Review Committee prior to the submission of a full proposal. Following approval of the LOI, the full proposal may be submitted at the next application deadline.*

Letter of Intent

The LOI should be one page and include the following information:

- 1. Principal Investigator
 - a. Full name, degree(s), title(s), VA/University Affiliations
 - b. Office address, phone, fax, email address
- 2. Names of other key personnel
- 3. Title and brief description of proposed research including:
 - a. Specific aims
 - b. Scientific rationale
 - c. Brief description of methods
 - d. Significance to VA

4. (*Optional*) Include names (up to 3) of potential reviewers and indicate their pertinent area of expertise. Note: reviews are conducted at the opposite side of the state from the submission, i.e., Pittsburgh reviews are conducted by individuals in Philadelphia and vice versa. Spoke sites will be categorized by their east and west location and associated with the corresponding hub. In addition, please refer to the NIH policy at <u>http://grants2.nih.gov/grants/peer/COI Information.pdf</u> for reviewer eligibility guidance.

The LOI will be reviewed within three weeks of the due date for the month in which it is submitted. Approval of the LOI will be based on the following criteria:

- a. Proposed project being within the scope of the MIRECC
- b. Significance of the project to the VA
- c. Plans for conducting future research at the VA
- d. Availability of funds in the current fiscal year
- e. Likelihood the completed pilot will lead to subsequent independent funding

LOIs should be emailed to Sara Chapman at <u>sara.chapman@va.gov</u> no later than noon on the last Friday of the month. LOIs received after this time will be considered as a submission for the subsequent month.

Proposal Preparation

The proposal should follow the format outlined below. *Please note that VA Forms can be found on* <u>http://www.research.va.gov/funding</u>.

- 1. MIRECC Pilot Project Fund Application Cover Page (see attached).
- 2. Abstract (VA Form 10-1313-2)



3. Budget and budget justification (VA Forms 10-1313-3 and 10-1313-4). Provide job descriptions for all support personnel.



4. NIH Biographical Sketch for the Principal Investigator and all Co-Investigators (blank and sample attached). Further information can be found on the NIH website <u>here</u>.



biosketch-blank-for mat-rev-10-2021.doc



non-fellowship-bio sketch-sample-2021.

- 5. In the application from a new investigator, include a letter of commitment from the Mentor and the Mentor's CV. Note: the Mentor need not be a VA employee. For a senior and/or currently funded investigator, include a letter stating the reason that pilot funding is being requested and how this will lead either to the development of new methods or support exploratory investigation in an area of research that represents a significant change in direction from that of the investigator's previous work.
- 6. Research Plan

The Research Plan should include sufficient information needed for evaluation of the project, independent of any other document. Do not exceed 5 pages for items a-d. All tables, graphs, figures, diagrams and charts must be included within the five-page limit. Full-sized glossy photographs of material such as electron micrographs or neuroimaging scans may be included in the Appendix; however, a photocopy of each must also be included within the page limitations of the Research Plan. The 5-page limit will be strictly enforced. Applications that exceed this limit, or do not conform to the font size limitations, will be returned without review.

- a. **Specific Aims.** List the broad, long-term objectives and what the specific research proposed in this application is intended to accomplish. State the hypotheses to be tested.
- **b. Background and Significance**. Briefly sketch the background leading to the present application, critically evaluate existing knowledge, and specifically identify the gaps the project is intended to fill. State concisely the importance and health relevance of the research described in this application by relating the specific aims to the broad, long-term objectives.
- c. Preliminary Studies/Progress Report. Use this section to provide an account of the Principal Investigator/Program Director's preliminary studies pertinent to the application and/or any other information that will help to establish the experience and competence of the investigator to pursue the proposed project. The complete references to appropriate publications and manuscripts submitted or accepted for publication may be listed and are not part of the page limitations. No more than 10 such items of background material may be submitted in the appendix.
- d. Research Design and Methods. Describe the research design and the procedures to be used to accomplish the specific aims of the project. Include how the data will be collected, analyzed, and interpreted. Describe any new methodology and its advantage over existing methodologies. Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims. As part of this section, provide a tentative sequence or timetable for the project. Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised.
- e. Human Subjects. Include a description of the subject population, sources of research material, recruitment and consent procedures, potential risks, risk management procedures, and evaluation of risk/benefit ratio. For human subjects, include a copy of the consent procedures.
- **f. Vertebrate Animals.** Include a description of the study animals and sources of animals, potential risks, risk management procedures.
- g. Literature Cited.

The Research Plan (sections a-d) should not exceed 5 single-spaced pages and should be submitted with the margins being 1 inch and the font being 12-point or higher. References should not exceed two pages and do not count against the 5-page limit.

When human subjects are used, a copy of the consent forms and the results of the initial review of the protocol approved by the local Institutional Review Board and other relevant committees (e.g. Radiation Safety, Transplant Council, etc.) must be forwarded *before funding will be awarded*.

When animals are used in the project, full compliance with all relevant NIH guidelines must be observed, and a copy of the local IACUC approval appended *before funding will be awarded*.

Proposal Submission

Applications should be emailed to <u>sara.chapman@va.gov</u> no later than noon on the last Friday of the month (e.g., 10/25/24, 11/29/24). Applications received after this time will be considered as a submission for the subsequent month.

Only one application per individual will be accepted. However, in some instances, revised resubmissions of previously reviewed applications will be considered. The application will be reviewed within eight weeks of the due date for the month in which it is submitted. Incomplete applications, or applications not prepared in accordance with the instructions, will not be considered and will be returned to the applicant.

FURTHER INFORMATION

Any questions relating to the application submission should be directed to Sara Chapman, MS, OTR/L (<u>sara.chapman@va.gov</u>). Any further questions regarding the MIRECC research mission can be directed to the MIRECC Co-Associate Director for Research, Dr. Henry Kranzler (<u>kranzler@pennmedicine.upenn.edu</u>) at the Corporal Michael J. Crescenz VAMC in Philadelphia VAMC or the Co-Associate Director for Research, Dr. Vish Nimgaonkar (<u>vishwajit.nimgaonkar@va.gov</u>) at the VA Pittsburgh Healthcare System.

Cover Page	
Principal Investigator	
Last Name, First Nar	me, Middle Initial
Date entered on VA Duty	Degree of VA Employment in Eighths
VA/University Title(s)	Telephone #
Primary Department/Division	Email Address
Mailing Address	DegreeYear Awarded
Category of Research (e.g., Clinical, Basic, HSR&D, Qualitative, etc.)	
Project Title	
Location/Facility for Completion of the Project	
(Remember to attach CV of your mentor for the mentor.) <i>Note: the Mentor need not be a VA er</i>	
Human Subjects Yes No	
Local IRB Approval Date (Anticipated)	
Vertebrate Animals Yes No	
Starting Date of Project	Ending Date of Project
Total amount Requested \$	Note: No more than \$25,000 may be requested.
If an award is made, the awardees will abide by all Review Board (IRB) and the MIRECC Research Re agreements between the local IRB and other Instit	eview Committee. In addition to any cooperative
Signature of Principal Investigator	Date
Signature of Principal Investigator's Supervisor	Date