

2024 Whole Health Rapid Start Funding Opportunity

The mission of the Pain/Opioid CORE is to enhance collaboration and advance research related to pain and opioid use disorder.

Purpose

The purpose of the Pain/Opioid CORE Whole Health Rapid Start program is to support <u>rapid quality improvement (QI) and program evaluation</u> on Whole Health for pain and/or opioid use disorder (OUD). We will fund 1- or 2-year projects that are a) consistent with CORE and Office of Patient Centered Care & Cultural Transformation (OPCCCT) priorities listed below and b) likely to meaningfully inform future applications for VA funding (e.g., IIR, Service-Directed Research, QUERI project, Pain and Opioid Use (POU) actively-managed portfolio), answer priority questions (secondary analysis), or advance implementation and/or expansion of Whole Health programs.

Rapid QI and Evaluation Projects

Non-Research Designation is Required for All Projects. Because the funding for these projects will come from the OPCCCT, a VA program office, projects <u>must</u> be designated as non-research. Before a project can be initiated, Pain/Opioid CORE leadership will facilitate a letter from OPCCCT, or another operations partner as appropriate, designating the work as non-research and/or quality improvement. In some cases, local institutional review boards (IRBs) will also need to review projects to secure this non-research determination. More information about conducting projects with non-research determinations within the VA can be found here (<u>ProgramGuide-1200-21-VHA-Operations-Activities.pdf (va.gov)</u>). Note: clinical trials are almost always considered research. We are interested in:

- Investigators currently working in the pain and/or OUD area
- Applications from early career investigators
- Applications from investigators new to pain and/or OUD evaluation or research who plan future work in this area
- Applications that promote collaborations with clinical and/or operational partners on high priority topics
- Secondary analyses of previously collected data

Priorities

The Pain/Opioid CORE and OPCCCT will select projects that address program office priorities for FY24. Applicants should specify which of the following priorities and focus areas their project fits under.

Projects that evaluate the following:

- Effectiveness of Whole Health approaches and therapies (including complementary/ integrative health (CIH*), health coaching, Whole Health Partner peer-to-peer experiences) for pain and/or OUD**
- Approaches to enhance patient activation, engagement, and adherence to Whole Health approaches and therapies for pain and/or OUD

- Comparisons of treatment delivery strategies for Whole Health approaches (e.g., telehealth vs. in-person, group vs. individual, and brief vs. standard course) for pain and/or OUD
- Comparisons of Whole Health approaches and therapies for pain and/or OUD to pharmaceutical use or other interventions
- Outcomes of combining or sequencing Whole Health interventions for pain and OUD
- Treatment dosing and maintenance strategies for Whole Health approaches for pain and/or OUD Implementation strategies to increase uptake of effective Whole Health interventions for pain and/or OUD
- Approaches to address clinician and health system barriers to use of evidence-based therapies including Cognitive Behavioral Therapy (CBT), Acceptance and Commitment Therapy (ACT), and Mindfulness Based Stress Reduction (MBSR) for pain and/or OUD
- Downstream effects on clinicians when comprehensive pain care is used versus traditional biomedical pain care (such as effects on clinician satisfaction or attitudes toward patients with chronic pain)
- Approaches to improve availability and reach of Whole Health approaches for pain and/or OUD
- Whole Health interventions to improve retention of patients in OUD treatment and reduce inappropriate discontinuation of MOUD by providers
- Effectiveness of psychosocial treatments and community/peer/family support strategies in patients with OUD
- Effectiveness of approaches to support opioid analgesic tapering in chronic pain (e.g., collaborative care, tapering protocols, nondrug therapies, clinician training, patient education, interventions to enhance engagement, technology-based interventions)
- Approaches to enhance patient activation, engagement, and/or adherence with behavioral and movement therapies among patients with pain and/or OUD
- Effectiveness of novel care delivery approaches such as peer-delivered care for pain and/or OUD
- Projects that evaluate implementation and/or uptake of Whole Health approaches and therapies (including CIH*), health coaching, Whole Health Partner peer-to-peer experiences) for pain and/or OUD specifically among groups at greater risk of health disparities

*CIH can include both evidence-based therapies currently covered by VHA medical benefits and other therapies with less evidence being offered at a limited number of VAMCs. More information on VA policies on CIH available here Integrative Health Coordinating Center-Home (sharepoint.com)

**OUD can be with or without comorbid substance use disorders

Timeline

Submission Deadline: January 16, 2024, at 11:59 PM PST

Estimated Notification of Funding and Start Date: March 15, 2024

Project Duration: Projects should be completed within either 1 or 2 years.

Eligibility

- Principal investigator (PI) must have a minimum 5/8ths VA appointment (eligible for VA funding as PI).
- If the applicant is a fellow, a mentor with a 5/8ths VA appointment must serve as the PI.
- Study team must include at least one currently HSR&D, RR&D, or CSR&D-funded investigator who has meaningful scientific involvement in the proposed project.

Project Duration

- Applicants may propose one- or two-year projects (must be completed by 9/30/2025). If multi-fiscal year (FY24 and FY25) proposals are submitted, projects will be evaluated at the end of the first fiscal year and continued funding will be decided by OPCCCT based on their priorities, project progress, and the availability of funds.
- Importantly, project funds provided to support work within a given fiscal year must be **spent** within that fiscal year. See the budgetary details below.

Budget

- Project budgets can range from \$10,000 to \$50,000 per year.
- Allowable Costs: PI effort, personnel (e.g., research assistant, project coordinator, statistician), supplies or other items that can be obtained within the 1-year time frame. External contracts not already in place will typically not be feasible to initiate within the 1-year time period. Hiring new personnel and acquiring IT will not be feasible in the 1-year time frame and should not be requested.

Application/Review Process

Proposals must be **emailed as a single PDF document to the Pain/Opioid CORE at PainOpioidCORE@va.gov.** Proposals not submitted as a single PDF will not be accepted.

Proposals will be reviewed by the CORE Pls, Office of Patient Centered Care & Cultural Transformation leadership, the CORE Internal Leadership Committee, and other Subject-Matter Experts. Applicants may be invited to present their project, respond to reviewer questions about the proposed study, or make revisions. Scoring will be based on the following modified HSR&D criteria:

- **Significance**: Scientific quality and potential of the evaluation/QI project to answer priority questions or further implementation and/or expansion of Whole Health programs. Does the proposed work have the potential to have a substantial impact on advancing health and health care of Veterans?
- **Feasibility:** Likelihood that the project can be completed in the one- to two-year time frame. Does the project qualify as non-research as required by the RFA?
- **Approach**: Appropriateness of the evaluation design and specific methods to the stated objectives of the study. The evaluation plan should be well-reasoned and feasible to complete in one to two years within the budgetary limits. Is the approach the best way to advance science in this area? Are methods adequate to answer the stated evaluation question(s)?
- Relevance to OPCCCT priorities as outlined in this RFA: Does the study advance knowledge in an area identified as an OPCCCT priority as outlined in this RFA.?
- Investigator/Project Team Qualifications: Do the PI and research team have the necessary knowledge and background for the project?
- Preference Points: Awarded to early career investigators (more information in FAQs).

Submission Requirements

Proposals should be submitted as a single PDF proposal containing the following:

- Pain/Opioid CORE Rapid Start Funding Proposal cover sheet (attached), including proposal title, PI and Co-Investigator names and affiliations (VA and non-VA), and PI's VA 8ths.
- Specific Aims (up to ½ page)
- Summary of Project (approximately 2 pages)

- Background & Significance including statement of why the proposed work is consistent with the priorities of this special RFA. (Up to ½ page)
- Methods
- Timeline / Milestones
- Indicate why the proposed work meets non-research designation according to section 5a-c in ProgramGuide-1200-21-VHA-Operations-Activities.pdf (va.gov) .
- Budget and brief budget justification (up to ½ page)
- References
- Biosketches and Other Support forms of PI and Co-Investigators
- For early career investigators, a letter of support must be included from a senior coinvestigator/mentor providing guidance on the proposed project (up to 1 page).

Award Requirements

- Given the time-sensitive nature of this funding opportunity, project activities should begin as soon as possible and no longer than one month following award notification. Proposals should address timing of activities that may need to be completed before project initiation (e.g., hiring, IRB and data use approvals).
- Awardees will be invited, and strongly encouraged, to present their proposal to the <u>Pain/Opioid</u> <u>CORE Veteran Engagement Panel (VEP)</u> for feedback on one or more aspects of their proposed project.
- Awardees will be encouraged to present their works-in-progress and/or completed work in relevant pain and/or opioid related seminar series (e.g., VA Spotlight on Pain Management, Medication Addiction Treatment in the VA (MAT-VA)/SUD Journal Club, SCOUTT Initiative, etc.)
- Awardees will provide Pain/Opioid CORE leadership with:
 - Quarterly updates (templated form) summarizing activities and progress
 - A final report summarizing project results and impacts within 3 months of the project end date will be required along with a brief slide presentation appropriate for OPCCCT leadership summarizing key project findings, lessons learned, and implications for practice.
 - Acknowledgement of Pain/Opioid CORE Rapid Start Funding in all publications and/or presentations stemming from the award
 - Notification of future impact on patient care or grant applications and awards informed by CORE starter funds
- Pls of multi-year projects will provide OPCCCT with an updated project plan for year 2 to inform continued funding decisions.

Contact Information

For questions about the 2024 Whole Health Rapid Start Funding Opportunity, or to be added to the Pain/Opioid CORE mailing list, please contact PainOpioidCORE@va.gov or Kathryn LaChappelle, MPH at kathryn.lachappelle@va.gov.

<u>Office hours</u> Teams meeting office hours will be held on 2 occasions to answer questions, with representatives present from the Pain/Opioid CORE and the OPCCCT:

December 15, 2023, 1:00-2:00pmEST:

Join on your computer, mobile app or room device

Click here to join the meeting

Meeting ID: 247 537 645 246

Passcode: tS3rAc

Download Teams | Join on the web

January 5, 2024, 1:00-2:00pmEST:

Join on your computer, mobile app or room device

Click here to join the meeting

Meeting ID: 271 110 257 435

Passcode: x2rbs7

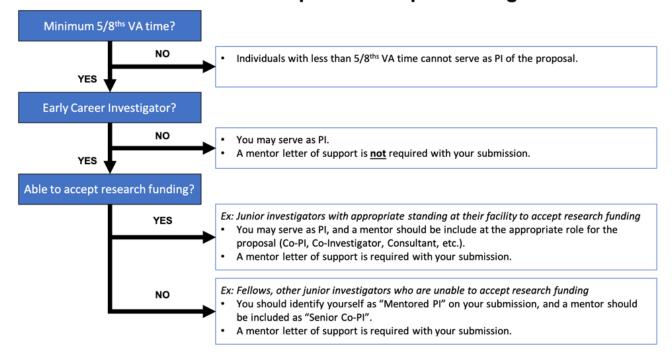
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Frequently Asked Questions

How do I know if I am qualified to serve as PI of a Pain/Opioid CORE Rapid Start proposal?

All study PIs must have a minimum of 5/8ths VA time. At least one PI on the proposal must have appropriate standing to accept research funding at their facility. Please check with your local Research Office if you are unsure if you can accept funding. Junior investigators who are unable to accept independent research funding (i.e., fellows) are eligible to identify themselves as the Mentored PI of the proposal while listing a senior investigator as a Mentoring Co-PI who will serve as the project's contact PI. The decision aid below may be useful to determine whether you are qualified to serve as PI of a proposal.

Pain/Opioid CORE Rapid Start Funding Opportunity Decision Aid for Proposal Principal Investigators



I was previously awarded a Pain/Opioid CORE Rapid Start Funding award as a Pl. Am I eligible to apply for a second award?

Applicants may not have two active rapid start awards as PI/mPI at the same time. Previous awardees are eligible to apply for a second Rapid Start Funding award if they have fully completed their previously awarded project. Previous awardees are eligible to serve as co-investigators on additional proposals.

Are multiple principal investigators allowed on a proposal?

Yes, proposals may include multiple Pls. However, the proposal should clearly outline how each Pl's contributions are needed to complete the proposed research. A single contact Pl should be clearly identified.

Can Rapid Start Funding be used to fund a study team member on an IPA?

Funds distributed from the Pain/Opioid CORE may be used to support members of the study team external to the VA on an IPA. Local rules and regulations must be followed regarding IPAs. Please contact your Research Office for additional questions about IPAs and to discuss feasibility of one-year support funding the individual IPA.

Who is considered an early-career investigator?

Broadly, all trainees are considered early career investigators. More specifically, applicants without previously awarded funding beyond local funding (i.e., Locally Initiated Projects) and applicants on an active career development award are considered early career investigators by the Pain/Opioid CORE.

Is a mentor letter required with my submission?

If you are an early career investigator, a mentor letter is required with your submission. Please see the decision aid above for more information on when a mentor letter is required.

What format is acceptable for submitted biosketches?

Biosketches should follow the NIH or VA submissions format. Additional information, including a biosketch template, is available online from NIH (https://grants.nih.gov/grants/forms/biosketch.htm) and on the VA Intranet (http://vaww.research.va.gov/funding/electronic-submission.cfm).

What are "Other Support" forms?

Other Support forms outline additional current or pending resources (including financial support) available to study investigators during the award period. Applicants should use the NIH format, with more information available at https://grants.nih.gov/grants/forms/othersupport.htm. If an investigator does not have other research support, please include a single page in your submission indicating so.

Can a non-VA trainee currently working with VA investigators submit a proposal?

Generally, no, since all identified PIs must have a minimum of 5/8ths VA time. VA investigators may submit a proposal with co-investigators that have less than 5/8ths VA time.

I'm a VA clinician new to research, with facility support to conduct the proposed research. Am I eligible to apply?

Yes, we encourage interest and proposals from VA clinicians who are new to research. Your study team should include at least one current VA-funded investigator with meaningful scientific involvement in the proposal.

I have questions about mentoring. Is there someone I can contact at the Pain/Opioid CORE for more information on mentoring in pain/opioid research?

A high priority of the Pain/Opioid CORE is to facilitate career development of early career investigators and investigators new to pain or opioid-related research through collaboration and professional development activities. For more information on the Pain/Opioid CORE's mentoring and career development opportunities, please email Kathryn.lachappelle@va.gov and Tracy.Sides@va.gov.

How will I know that my proposal was received by the Pain/Opioid CORE?

You will receive an email confirming receipt within 1-2 business days of submission.



2024 Rapid Start Funding Proposal Cover Sheet

1. Proposal title: 2. Principal investigator information 2a. PI: 2b. PI affiliation(s) (VA and non-VA): **2c. PI VA employment status** (Check all that apply) ☐ Full-Time VA Paid Employee ☐ Part-Time VA Paid Employee □ VA Fellow/Trainee Other: 2d. PI VA 8ths: 3. Is the PI a fellow or early career/junior investigator being mentored by a senior investigator on the proposed project? Yes No (If Yes, please complete sections 3a-d) 3a. Senior investigator: 3b. Senior investigator affiliation(s) (VA and non-VA): 3c. Senior investigator VA employment status (Check all that apply) ☐ Full-Time VA Paid Employee ☐ Part-Time VA Paid Employee ☐ VA Fellow/Trainee Other: 3d. Senior investigator VA 8ths: 4. Co-Investigators, with affiliation(s) (VA and non-VA): 5. Total budget requested: 6. How did you hear about the Pain/Opioid CORE Rapid Start Funding Opportunity? (Optional, Check all that apply) ☐ Pain/Opioid CORE Email ☐ Other HSR&D CORE Communications ☐ Pain/Opioid CORE Newsletter ☐ Previous Applicant Referred from mentor/other collaborator ☐ Pain/Opioid CORE Website ☐ Research Office/COIN Communications ☐ Program Office Communications Other: