U.S. Department of Health & Human Services • National Institutes of Health

National Center for Complementary and Integrative Health

NIH-DoD-VA Pain Management Collaboratory Funding Initiative: Technical Assistance Webinar for AT17-001 and AT17-002

January 23, 2017

Questions?

- Questions today? NCCIHwebinarQ@mail.nih.gov

- Questions after the webinar? NCCIHwebinarQ@mail.nih.gov or direct to a specific FOA contact

Iraq and Afghanistan Wars

- Since 2001, more than 2.5 million service members were deployed for Operations Enduring Freedom, Iraqi Freedom, and New Dawn.

- Many of these service members experienced multiple deployments.
- A high number survived severe injuries that in previous wars would have resulted in death.
- Pain is a particularly salient concern for returning service members and veterans.
- Pain coexists with other problems (mental health, substance abuse, sleep, etc.).

NIH-DoD-VA Pain Management Collaboratory

Funding Opportunity Announcements (FOAs):

- AT17-002: NIH-DoD-VA Pain Management Collaboratory Coordinating Center (U24)
- AT17-001: NIH-DoD-VA Pain Management Collaboratory Pragmatic Clinical Trials Demonstration Projects (UG3/UH3)

Letters of Intent due February 1, 2017; Applications due March 3, 2017

Include in Letters of Intent:

- Descriptive title of proposed activity
- Name(s), address(es), and telephone number(s) of the PD(s)/PI(s)
- Names of other key personnel
- Participating institution(s)
- Number and title of the funding opportunity

The letter of intent should be sent to:

Martina Schmidt, Ph.D., NCCIH
Email: SchmidMa@mail.nih.gov

NIH-DoD-VA Pain Management Collaboratory

- **NIH:** NCCIH, NINDS, NIDA, NIAAA, NICHD (NCMRR), ORWH, NINR
- **DoD:** Clinical Rehabilitation Medicine Research Program (CRMRP), Military Operational Medicine Research Program (MOMRP)
- **VA:** Health Services Research and Development (HSRD)

This Initiative Builds Upon Three Sets of Efforts

- Collaborations between the NIH, DoD, and VA over many years
- NIH Health Care Systems Collaboratory
- NCCIH Council Working Group Report “Strengthening Collaborations with the U.S. Department of Defense and U.S. Department of Veterans Affairs: Effectiveness Research on Mind and Body Interventions”

NIH-DoD-VA Pain Management Collaboratory

Overall Goal: Develop the capacity to implement cost-effective, large-scale clinical research in military and veteran health care delivery organizations focusing on nonpharmacologic approaches to pain management and other comorbid conditions.

The Details

- Up to 6-year cooperative agreement
- AT17-002: Coordinating Center (U24)
- AT17-001: Pragmatic Trials Demonstration Projects (UG3/UH3)
- Studies are conducted in health care systems serving military personnel, veterans, and their families
- Applications focused on the military health care context should include military researchers, and applications focused on the veteran health care context should include veteran researchers

Outcomes

- **Primary:** pain and pain reduction, ability to function in daily life, quality of life, and pain medication usage/reduction/discontinuation.

- **Secondary:** assessing comorbid conditions or those co-occurring with high frequency in this population.

Types of Nonpharmacologic Approaches

- Mindfulness/meditative and movement interventions
- Manual therapies
- Neuromodulation
- Psychological and behavioral interventions
- An integrative approach that involves more than one intervention. Of special interest are integrated models of multimodal care that are delivered in different settings.

Award Budget and Funds Available

U24:

- Direct costs requested for the first 3 years may not exceed $1.3 million per year. Direct costs for years 4 to 6 may not exceed $1.0 million per year
- NIH intends to commit $2 million in FY2017 to fund 1 award (NCCIH, NIDA, ORWH).

UG3/UH3:

- The UG3 phase budget is limited to $500,000/year in direct costs for up to 2 years. The UH3 phase budget is limited to $1 million/year in direct costs for up to 4 years.
- Collectively, the agencies intend to fund approximately 5 to 7 UG3 awards.

The Coordinating Center (U24)

- Will develop, adapt, and adopt technical and policy guidelines and best practices for the effective conduct of pragmatic clinical trials in partnership with health care systems focused on military personnel, veterans, and their families.
- Will work collaboratively with, and provide technical, design, and other support to Demonstration Project teams, to develop and implement a research protocol.
- Will widely disseminate NIH-DoD-VA Pain Management Collaboratory-endorsed policies and best practices and lessons learned for implementing research within health care settings that deliver health care to U.S. military personnel, veterans, and their families.

The U24 will not:

Provide data coordination activities for the pragmatic trials. Each trial has to have their own complete plan for data collection, analysis, quality control, etc.

Research Strategy for U24

- 30 pages for Research Strategy section
- Willingness to cooperate with Demonstration Project teams, the NIH, DoD, and VA in the development and design of research approaches, methods, processes, policies, and tools used in this program
- Provide expertise to lead 5 to 7 workgroups
- Team's experience conducting pragmatic trials in BOTH military and veteran health care settings such that they can provide technical expertise to other investigators proposing to do pragmatic trials in these settings
- Resource and Software Sharing Plans

Funding Agency Project Officers and/or Scientists

Demonstration Projects

Steering Committee

Cores/Workgroups

Coordinating Center

Cores/Working Groups

- Guide and support Demonstration Projects
- Disseminate knowledge
- Chair from Coordinating Center and representatives from NIH and Demonstration Projects

Electronic Health Records

Stakeholder Engagement

Phenotypes/Outcomes

Ethical/Regulatory

Study Design/Biostatistics

Data Sharing

The Pragmatic Trials Demonstration Projects (UG3/UH3)

- Phased cooperative agreement research applications to conduct efficient, large-scale, pragmatic clinical trials Demonstration Projects.
- These projects will be funded as phased awards with a 2-year planning phase (UG3) and 2 to 4 year implementation phase (UH3).
- All projects will be milestone-driven, and moving to the implementation phase (UH3) will be dependent upon the successful progress made during the planning phase (UG3).
- The Demonstration Projects will generally be performed within large health care systems that utilize electronic health records (EHR) to leverage data collection that occurs in health care delivery rather than requiring independent research data collection.
- Teams can implement methods to enhance completion of EHR data with patient-reported outcomes when it is needed.

UG3/UH3 Research Objectives

- The pragmatic trials should meet the following criteria specified, which are also described in http://www.cmaj.ca/content/180/10/E47.full.
- The pragmatic trial should test an intervention, or compare interventions (e.g., treatments, preventive actions, policies, or organizational changes) that are robust, apply broadly to patient populations and are suitable for use in health systems serving military personnel, veterans, and their families, with the broad goal of determining whether the intervention improves health and adds value to the utilization of health care resources.

Milestones and UG3/UH3 Transition

- Projects should include well-defined milestones for the UG3 and annual milestones for the UH3.
- Three months prior to the date of the planned transition, the applicant will be required to submit a detailed transition request for the UH3 phase. UH3 transition requests will undergo an administrative review to determine whether the Demonstration Project will be awarded the UH3.
- Transition to the UH3 phase of the project will occur only if an administrative review process recommends that the UG3 planning milestones have been successfully met, that the UH3 phase can proceed with confidence of success, and availability of funds.

UG3/UH3 Research Strategy

- Research strategy section is limited to 30 pages.
- Budgets for both phases should be included.
- Applications must budget for project PD(s)/PI(s) travel to attend two, one-and-a-half-day NIH-DoD-VA Pain Management Collaboratory program meetings in the first year, and an annual meeting in subsequent years in the greater Washington, D.C., area.
- Letters of support must be included from Health Care System Partners.
- Resource and Data Sharing Plan

VA Research Focus

Sufficient evidence exists for the inclusion of yoga, tai chi, and exercise as first-line, recommended therapies for chronic musculoskeletal pain. VA would like to see implementation in clinical practice and improvement in patient retention.

Some questions of interest:

- Conduct pragmatic trials to understand VA care delivery. Develop strategies to assess high-quality pain care and compare different treatment models. Examine the feasibility of delivering collaborative care remotely.
- Examine effect of combining regular treatments with other therapies, e.g. assess optimal sequencing of acupuncture, massage, chiropractic, exercise/movement with other nonpharmacologic and pharmacologic approaches.
- Study minimum effective dosage and assess duration of effect. Compare different levels of model intensities.
- Identify effective strategies to engage and sustain benefits from these therapies. Also determine patient characteristics that may predict treatment response.
- Long-term prospective observational study of pain treatment, including psychological and behavioral therapies.
- Identify optimal self-management strategies, i.e., group visits, health coaching, self-treatment.
- Develop a consensus set of outcome measures to be used in pain research.
- Test the effectiveness of community-based interventions for Veterans.

DoD Pain Management Capability Gaps

- Better chronic pain management strategies for primary care providers in non-deployed settings
- Lack of knowledge of patient outcomes following chronic pain management treatment—evidence-based practice lacking
- Inadequate treatments for chronic pain management
- Limited strategic communication approaches for educating providers, patients, family members, and unit leaders
- Chronic pain management following trauma and in resource-limited environments
- Inadequate knowledge of the operational utility of chronic pain management far-forward
- Lack of clinical practice guidelines for best practices for assessment and management of chronic pain in a rural/austere environment

Pragmatic Trial Research Questions

- Studies to test the effect of system level innovations to improve implementation of established guidelines for nonpharmacologic approaches to pain management and comorbid conditions
- Studies focusing on testing the timing, optimum components, and overall benefit of an individualized integrated package of nonpharmacologic modalities such as exercise, mind and body therapies, and other complementary health approaches
- Evaluation of team-based versus provider-driven models of health care delivery, particularly in settings in which military personnel or Veterans normally receive care
- Evaluation of other factors critical to optimize pain care in primary care settings
- Assessment of the effectiveness of integrative pain management strategies to reduce the transition from acute to chronic pain, for example in the peri-operative period
- Evaluating sex and gender differences for optimizing treatment

Program Contacts

- NCCIH: Eve Reider, ereider@mail.nih.gov
- VA: Ranjana Banerjea, Ranjana.Banerjea@va.gov
- CRMRP, DoD: Smita Bhonsale, smita.i.bhonsale.ctr@mail.mil
- MOMRP, DoD: Ronald Hoover, ronald.l.hoover.civ@mail.mil
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- NINDS: Michael Oshinsky, michael.oshinsky@nih.gov
- NIAAA: Mark Egli, megli@willco.niaaa.nih.gov
- NICHD (NCMRR): Alison Cernich, Alison.Cernich@nih.gov
- ORWH: Lisa Begg, beggl@od.nih.gov
- NINR: Martha Matocha, matocham@mail.nih.gov

Once your application arrives at NIH

1. Administrative Review (plus responsiveness)
2. Assembling the Review Panel
3. Reviewers evaluate/discuss the applications
4. Scores and Summary Statements are released

Administrative Review

Completed at CSR and NCCIH

- Assesses if all FOA required elements are included in the application (Is your application complete?)
- Compliance with RFA-AT-17-001 and RFA-AT-17-002 specific requirements
- **Applications that are incomplete, noncompliant, and/or nonresponsive will not be reviewed!!!!!!**
- **=> Keep in mind, information "accidently" left out of the application cannot be accepted as post submission material except as stated in NOT-OD-13-030**
- **=> Watch out for words like "must" and "required" and be mindful of words like "should" and "expected"**

Eligibility Requirements

- Demonstration Projects:
  - UG3 is limited to $500K in direct costs/year (up to 2 years)
  - UH3 is limited to $1 million in direct costs/year (up to 4 years)

- Coordinating Center:
  - $1.3 million/year (year 1-3)
  - $1.0 million/year (year 4-6)

- Multiple PIs are allowed
- PI(s) required 20% effort (30% for Coordinating Center)
- Foreign Institutions **are not** eligible to apply (non-US components of US Organizations **are** eligible)
- Foreign components **are** allowed

Submission Format/Instructions

(Demonstration Projects)

- Both UG3 and UH3 phases in a **SINGLE** application

- Research Plan:
  - Specific Aims for UG3 and UH3 phase (1 page)
  - Research strategy for UG3 and UH3 phase (30 page limit)
    - Rationale and plans for UG3 phase
    - **Milestones** for UG3 phase (required)
    - Rationale and plans for UH3 phase
    - **Milestones** for UH3 phase (required)
  - **Letters of Support** from each of the HCS partners relating their commitment to the proposed research (required)
  - **Resource and software sharing plans** (expected)

- Appendix materials can be included

Submission Format/Instructions
(Coordinating Center)

- Research Plan:
  - Specific Aims (1 page)
  - Research strategy (30 page limit)
    - Rationale and plans for the U24
    - *Coordinating Center Transition Plan* (expected)
    - **Resource and software sharing plans** (expected)

- Appendix materials can be included

Allowable Appendix Material

- Applications submitted for due dates on or after **January 25, 2017**:
  - Clinical trial protocols
  - Investigator's brochure from Investigational New Drug (IND)
  - Blank informed consent/assent forms
  - Blank surveys, questionnaires, data collection instruments
- **NOT-OD-16-129:** ***Consequences for submitting disallowed appendix materials***: Applications submitted for due dates on or after January 25, 2017 will be withdrawn and not reviewed if they are submitted with appendix materials that are not specifically listed in this Notice, or the FOA, as allowed or required.

Allowable post-submission material

(NOT-OD-13-030 and NOT-OD-10-115)

- Due date will be **30 days** before the review meeting date!!!!!
- Up to 3 pages describing updated Specific Aims or Research Strategy, late-breaking research findings and/or new letters of support or collaboration
- Revised budget page(s) (e.g., change in budget request due to new funding or institutional acquisition of equipment)
- Biographical sketches (e.g., change in senior/key personnel due to the hiring, replacement, or loss of an investigator)
- Letters of support or collaboration resulting from a change in senior/key personnel due to the hiring, replacement, or loss of an investigator
- Adjustments resulting from natural disasters
- Adjustments resulting from change of institution (e.g., PI moves to another university)
- News of an article accepted for publication (a copy of the article should **not** be sent)
- News of a professional promotion or positive tenure decision for any Program Directors/Principal Investigators and Senior/Key Personnel

Review Criteria I

Scored Criteria

- Significance
- Investigators
- Innovation
- Approach
- Environment

Additional Review Criteria:

- **Milestones** (Demonstration Projects)
- Protection of HS
- Inclusion of Women, Minorities and Children
- Biohazards

⇒All these aspects are considered by reviewers and they do influence the "Overall Impact" score of an application.

Additional Review Considerations

(will not be factored into the Overall Impact Score)

- Resources and Data Sharing and Software Sharing
- Select Agent Research
- Authentication of Key Biological and/or Chemical Resources
- Budget and Period of Support

Review Criteria II

⇒**Several review criteria/considerations as well as the language under the criteria/considerations in these FOAs are not standard; they are specific for these FOAs!**

⇒ **Please Read Carefully!!!!**

⇒ **Make sure to address <u>ALL</u> the aspects/questions outlined in the review criteria/considerations of the FOAs in your application!**

Summary – Important Dates

- Letter of Intent ***February 2, 2017***
- Application Due Date ***March 3, 2017***

- CONTINUOUS SUBMISSION POLICY **DOES NOT** APPLY
- LATE APPLICATIONS **MIGHT BE** ACCEPTED (please see NOT-OD-15-039 for details)

- Review Meeting ***June 2017***

  Roster available 30 days prior to meeting
- Award Decision ***October 2017***

Questions?

- Questions today? NCCIHwebinarQ@mail.nih.gov

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