Approaches to Pain Management: NCCIH-focused Research Highlights

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NCCIH
Proposed HEAL Pipeline of Pain Programs

**Discovery**
- Acute to Chronic Pain Signatures
- Discover and Validate Novel Targets for Safe and Effective Pain Treatment

**Preclinical Development**
- Preclinical Screening Platforms for Pain (human cells and animals)
- Development of Non-addictive Therapies to Treat Pain
- Discovery and Validation of Biomarkers, Biomarker Signatures, and Endpoints for Pain Indications

**Clinical Trials**
- Data and Asset Sharing Partnership
- Early Phase Pain Investigation Clinical Network (EPPIC) includes BACPAC
- Effectiveness Research Network (ERN)

**Implementation and Dissemination**
- Pragmatic and Implementation Studies for the Management of Pain (PRISM)
Strengthen the national capacity to implement cost-effective large-scale research studies that engage healthcare delivery organizations as research partners.

http://rethinkingclinicaltrials.org/
New NCCIH HEAL Concepts Under Consideration

Pragmatic and implementation studies for the management of pain to reduce opioid prescribing (PRISM)

- Studies must be embedded in health care systems
- A coordinating center will assist project trials to improve rigor and achieve the project milestones
- Projects can propose to focus on:
  - System changes to improve adherence to evidence-based guidelines for pain management
  - Integration of evidence-based approaches for pain management into health care delivery
  - Some trials that will inform CMS health care policy about coverage decisions
Notice of Intent to Publish a Funding Opportunity Announcement for Pragmatic and Implementation Studies for the Management of Pain to Reduce Opioid Prescribing (PRISM) (UG3/UH3, Clinical Trials Optional)

Notice Number: NOT-AT-19-004

Key Dates

Release Date: November 02, 2018
Estimated Publication Date of Funding Opportunity Announcement: December 08, 2018
First Estimated Application Due Date: February 08, 2019
Earliest Estimated Award Date: September 01, 2019
Earliest Estimated Start Date: September 20, 2019

Notice of Intent to Publish a Funding Opportunity Announcement for Pragmatic Randomized Controlled Trial of Acupuncture for Management of Chronic Low Back Pain in Older Adults (UG3/UH3, Clinical Trial Required)

Notice Number: NOT-AT-19-005

Key Dates

Release Date: November 02, 2018
Estimated Publication Date of Funding Opportunity Announcement: December 08, 2018
First Estimated Application Due Date: February 15, 2019
Earliest Estimated Award Date: September 01, 2019
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NIH-DoD-VA Pain Management Collaboratory (PMC)

- Conduct large-scale “pain management” research (i.e. pragmatic clinical trials) in military and veteran health care delivery organizations
- Support the design and execution of high-impact Demonstration Projects (Currently 11 in planning phase)
- Build in implementation-methods during execution phase
- Make data, tools, best practices, and resources available to facilitate future similar research
Pain Management Collaboratory Coordinating Center (PMC³)

Robert Kerns, Cynthia Brandt, and Peter Peduzzi Yale University and Connecticut VA

- Works with Demonstration Project teams to develop, initiate and implement a research protocol;
- Coordinates and convenes Steering Committee of all PIs and federal partner representatives;
- Support Demonstration Projects via PMC work groups;
- Disseminate best research practices and within military and veteran health care systems
NICCH Clinical Research Funding Opportunities Across the Continuum

How does it work?
— Parent R01, R21 or R15
— Other active FOAs

Can the intervention be modified to enhance impact or adherence?
— Natural Product R33 or U01
— Mind Body R33, R34, or U01

Is it still effective when implemented in “real world” conditions?
— Natural Product Clinical UG3/UH3 & U24
— Mind Body Clinical UG3/UH3 & U24

Basic and Mechanistic
Translational
Intervention Refinement and Optimization
Efficacy/Effectiveness
Pragmatic Studies and Dissemination

Can the mechanistic impact be reliably measured in humans?
— Natural Product Clinical R61/R33
— Mind Body Mechanistic R61/R33

Does it work in comparison to an appropriate control?
— Natural Product Clinical UG3/UH3 & U24
— Mind Body Clinical UG3/UH3 & U24