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NIH HEAL INITIATIVE

NIH HEAL Initiative

Rebecca Baker, Ph.D., HEAL Director

Massachusetts Pain Initiative Annual Pain Symposium | October 13, 2022

NIH HEAL Initiative and Helping to End Addiction Long-term are service marks of the U.S. Department of Health and Human Services.

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An Evolving Crisis: Opioid Misuse, Overdose, and Pain

In 2022, pain is still a huge unmet need

- 50 million Americans have chronic pain
- 25 million have severe pain
- 20 million have high-impact chronic pain

NCHS Data Brief. 2020 Nov;(390):1-8. PMID: 33151145

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NIH HEAL Initiative: Scientific Solutions for the Crisis

- Over $2 billion in research
- 1,000 research projects
- 42 research programs
- Projects underway in all 50 states
- Released 50+ funding announcements since inception
  - *30+ released in FY22!*

From prevention, basic and translational research, clinical trials, to implementation science

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HEAL Research Portfolio: Overarching Themes

- Use a whole-person research focus
- Address health system problems and inequities
- Work with communities to bring research to life
- Use targeted discovery to understand biology of pain and addiction

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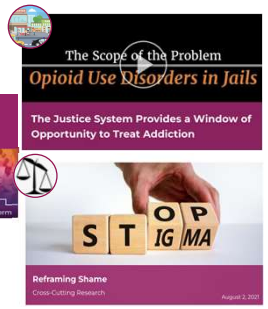
Research Spotlights



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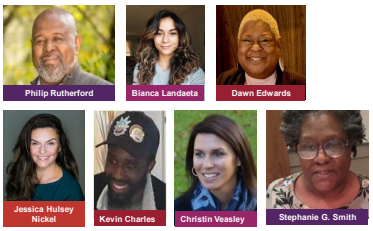
Voices of Lived Experience
HEAL Community Partner Committee



- Patients, advocates, liaisons, and family members
- Input on key issues faced by individuals affected by pain and addiction
- Identify, refine, and prioritize engagement activities and links to HEAL science

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HEAL is Enhancing Pain Management

Accelerating Research to Improve Pain Care

Discovery → Preclinical Development → Clinical Studies → Implementation/ Dissemination

Target Discovery
How can we find novel drugs?

Pre-screening platforms
What novel molecule, biologic, device might relieve pain?

Therapeutics Development
How can we develop or improve drugs & devices to relieve pain?

Biomarkers & Endpoints
How do we assess pain? Who will respond to a treatment?

Longitudinal Studies
Who will develop chronic pain?

Safety testing
Are new drugs safe?

Effectiveness Trials
Which therapies work best? For whom?

Pragmatic Trials
How do we get treatments into the clinic?

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Preclinical & Translational Research in Pain Management

Non-addictive therapeutic development programs

- Expanded analgesic therapeutics development program-planning studies and phased awards
- Novel targets and devices for pain relief, including small business grants
- Team-based research frameworks
- Screening and testing platforms, tissue chips and optimization research
- Studying pain in human genes & cells
- Expands workforce with expertise in overlap of pain and opioid use disorder

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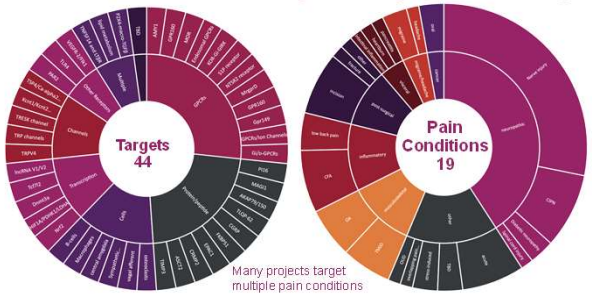
Overview of the HEAL Preclinical Target Discovery and Validation Program



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Clinical Research in Pain Management

Research to evaluate and compare pain management approaches

- Testing novel non-opioid medications and culturally/linguistically appropriate interventions
- Clinical trials of innovative pain therapies
- Discovering biomarkers and signatures
- Integrated management of chronic pain and opioid use disorder
- Health equity in pain management: interventions to mitigate effects of bias, stigma and socioeconomic barriers to pain treatment
- Enhancing the pain research workforce
- Leveraging existing data to better understand acute and chronic pain management

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HEAL Research Addresses Pain Across the Lifespan

- Back Pain Consortium
- Pain Management Effectiveness Research Network
- Pragmatic and Implementation Studies for the Management of Pain to Reduce Opioid Prescribing
- Hemodialysis Opioid Prescription Effort consortium
- Integrative Management of chronic Pain and OUD for Whole Recovery

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Relevance of Nursing in HEAL Clinical Pain Research

- Identify the most effective interventions and management strategies for pain while reducing reliance on opioids
- Improve functional and health outcomes
- Reduce pain across the continuum of acute to chronic pain associated with disease and pain presenting as disease itself
- Screen for chronic pain and opioid use disorder
- Address health inequities in pain and addiction
- Listen to the voice of lived experience

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Relevance of Physical Medicine and Rehabilitation in HEAL Research

- Clinical Trials
  - Back Pain Consortium Research Program
  - Early Phase Pain Investigation Clinical Network
- Prevention and Treatment:
  - Managing opioid misuse/low severity opioid use disorder
  - Role of sleep dysfunction
- Optimizing collaborative care (addiction, mental illness)
- Integrative Management of chronic Pain and OUD for Whole Recovery
- Restoring Joint Health and Function to Reduce Pain Consortium (RE-JOIN)
- Myofascial biomarkers

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NIH Pain Training Opportunities

- National consortium of mentors, institutions, and promising scholars
- Postdoc to-independent career transition awards in pain, substance use research
- Translational science training for early and mid-career Investigators
- HEAL Innovator Awards
- Illuminating novel targets for pain therapeutics
- Coordinated approaches to pain care in health care systems

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Advancing Health Equity in HEAL Research

- Advancing Health Equity in Pain Management
- Advancing Health Equity in Pain and Comorbidities
- Preventing Opioid Misuse and Co-Occurring Conditions by Intervening on Social Determinants
- Coordinated Pain Care in Health Care Systems
- Stigma research portfolio

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New HEAL Research Directions

Equity
Social determinants of addiction
Advancing health equity

Data & Evidence
Real world healthcare data
Secondary data analysis
Data 2 Action partnerships

Coordination, Collaboration & Integration
Pain management in systems of care
Research adoption partnerships

Reducing Stigma
HEAL
Community Partner Committee

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New Research: Restoring Joint Health and Function to Reduce Pain Consortium (RE-JOIN)

- Joint pain is cited by most individuals with opioid use disorder as a contributing factor in their use of opioids.
- Understand type and distribution of sensory neurons in two joints: knee and TMJ
- Understand factors leading to alterations in joint innervation (aging, sex, exercise, injury, joint degeneration or arthritis);
- Identify pathways shared across different types of joints
- Goal: modulate neuronal activation to reduce joint pain, prevent progression of joint deterioration, and, ultimately, restore healthy joints.

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New Research: PRECISION Human Pain Network

*P*rogram to *R*eveal and *E*valuate *C*ells-to-gene *I*nformation that *S*pecify *I*ntricacies, *O*rigins and the *N*ature of **Human Pain**

Aims to provide a better understanding of the molecular/cellular targets and mechanisms that specifically underlie *human* pain conditions

- Will generate comprehensive datasets of molecular signatures, cell types, and cellular function phenotypes that underlie human pain transmission and processing, using primary human tissues and cells.
- Will identify cellular bases underlying human susceptibility to different pain conditions and validate therapeutic targets for translational strategies.
- Will optimize and standardize protocols, assays, and data collection to allow integrated analysis across research centers

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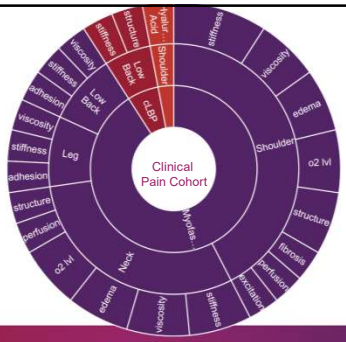
New Research: Biomarkers of Myofascial Tissues



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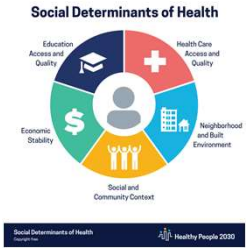
New Research: Advancing Health Equity in Pain Management

- Adapt and evaluate effectiveness of existing pain interventions in NIH designated populations that experience health disparities
- Develop and evaluate novel culturally-appropriate pain interventions in these populations
- Focus on targeted populations
- Extensive stakeholder & community engagement
- Consider SDOH barriers
- Pain and comorbid conditions: mental Health; opioid use disorder; chronic conditions



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New Research: Pain Analgesic Development Program

Goal: Accelerate development of novel, non-opiod, non-addictive analgesics

Discovery — Development

Hit/Lead Optimization → Lead Selection & Characterization → IND or BLA Enabling Studies → Phase I Clinical Trial

- Phased (UG3/UH3) grant with maximum 5 years of funding
- Grant includes access to NIH-sponsored ex-biopharma consultants and R&D CROs
- Entering applications can be at the Discovery or Development stage, and must include both UG3 and UH3 phases
- Project progression is milestone-driven and evaluated on an annual basis
- End Goals include formation of industry partnerships and readiness for Phase 2 trial
- Eligible organizations: academic institutions, small businesses and foreign institutions and components

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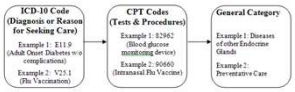
New Research: Secondary Analysis and Integration of Data

- Analyze existing human data from large, diverse national research cohorts to explore development of acute or chronic pain and its management
- Comparative effectiveness research outcomes
- Pain in underrepresented/understudied populations
- Genetic influences on pain
- Chronic overlapping pain conditions



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Open Funding Opportunities

Enter Keywords | Search | Advanced Search Options

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FOA #	FOA Title	Research Focus Area	Earliest Submission Date	Expiration Date	Posted Date
NOT-DA-22-056	Notice of Special Interest (NOSI): Developing Digital Therapeutics for Substance Use Disorders	Novel Medication Options for Opioid Use Disorder and Overdose	Wed, 04/06/2022	Thu, 12/07/2023	Fri, 02/18/2022
RFA-NS-22-050	HEAL Initiative: Discovery of Biomarkers and Biomarker Signatures to Facilitate Clinical Trials for Pain Therapeutics (UG3/UH3 Clinical Trial Optional)	Preclinical and Translational Research in Pain Management	Fri, 02/11/2022	Fri, 02/24/2023	Tue, 02/08/2022
NOT-NS-22-066	HEAL Initiative: Notice of Special Interest (NOSI) regarding the Availability of	Clinical Research in Pain Management	Fri, 04/29/2022	Sat, 04/30/2022	Tue, 02/08/2022

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NIH National Institutes of Health HEAL Initiative

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Research Concepts

A Research Concept describes the basic purpose, scope, and objectives of a potential solicitation of grants or contracts. Current concepts under development are listed below to alert researchers to areas of NIH HEAL Initiative research interest and to give researchers maximal lead time to plan projects. Past concepts that have converted to funding opportunities (FOAs) can be found at the bottom of the page. Please note that not every concept will lead to a FOA. The NIH HEAL Initiative bases this determination on scientific and programmatic priorities and the availability of funds, and a FOA may also differ in certain details from its originating concept. Please visit this page often for updates, subscribe to the HEAL Digest for updates, and view current (open) and past (closed) HEAL FOAs.

Research Concepts on this page:

- Translation of Research to Practice for the Treatment of Opioid Addiction
- New Strategies to Prevent and Treat Opioid Addiction
- Enhanced Outcomes for Infants and Children Exposed to Opioids
- Novel Medication Options for Opioid Use Disorder and Overdose
- Clinical Research in Pain Management
- Preclinical and Translational Research in Pain Management
- Past Concepts

https://heal.nih.gov/funding/research-concepts

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HEAL Scientific Solutions: Emerging Data Will Inform Practice

- Will acute pain turn chronic post-surgery?
- Who will respond to nonpharmacological treatments?
- Diverse data: imaging, high-throughput omics, sensory testing, psychosocial assessments, more

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HEAL Data Ecosystem

Make HEAL data accessible

- HEAL-generated data indexed and searchable, with clear routes to access
- Data management & sharing support
- User-friendly search & interface

Build the research community

- HEAL researcher engagement and consensus building, foster cross-awareness of research projects and drive collaborations
- Broad researcher, stakeholder & user engagement

healdata.org

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