



October 18, 2018

RE: HEAL initiative support of non-pharmacological approaches for pain management

Dear Colleagues:

Thank you for your commitment to improving pain care and your interest in optimizing research resources to benefit those who suffer with chronic pain. The National Institutes of Health (NIH) recently launched the HEAL (Helping to End Addiction Long-Term) initiative, an agency-wide program focused on advancing addiction research in the U.S. to reduce the risks of opioid use and misuse, and on pain research to diminish reliance on opioids by relieving pain with non-opioid approaches, including non-pharmacologic treatments. As you know, improving the management of pain is a core goal of the HEAL initiative, along with expanding therapeutic options for opioid addiction and overdose reversal. NIH has identified a set of research priorities reflecting urgent unmet needs across the lifespan, areas of promising scientific opportunity, and concrete strategies capable of providing rapid and durable solutions to the opioid crisis that will help improve treatments for opioid misuse and addiction and enhance pain management.

As the Director of NIH, I recognize the urgency to bring a broad array of treatment options to the clinical arena to ensure that individuals with chronic pain have access to integrated pain care that is tailored to their needs. I also recognize that integrated care goes beyond biomedical interventions to include other modalities, as appropriate, based on a biopsychosocial model of pain management.

Through the HEAL initiative, NIH is leveraging existing programs, establishing new infrastructure, and supporting a range of clinical studies to accelerate development of new treatments and provide an evidence base for best clinical practices across pain conditions. The HEAL initiative is setting up a pain clinical trial research network to support early phase 2 trials on the safety and efficacy of novel drugs and devices. This network will also support discovery research to identify biomarkers and endpoints to validate treatment targets, stratify patient populations for research and treatment, and predict patient response to treatment. NIH is also considering new projects, such as a pain management effectiveness research network (Pain ERN) to support phase 3 effectiveness trials. The Pain ERN will be poised to perform trials to test novel non-pharmacological treatments, as well as integrated treatments for many common pain conditions. Although there is already substantial evidence that non-pharmacological modalities are effective for certain pain conditions, we recognize that further research is needed to determine which patients will benefit from different modalities and how best to integrate these therapies into a multidisciplinary treatment plan. The clinical trial infrastructure established through the HEAL initiative will be well equipped to support studies to answer these questions.

NIH is also working with federal partners to prioritize research gaps for non-pharmacological treatments and plan the best pathways to address these gaps. The goals are to provide the foundation for implementing these treatments into large health care systems and lead to broader dissemination of their use. The Common Fund's Health Care Systems Research Collaboratory, which supports large-scale pragmatic trials, will be leveraged to support trials on non-pharmacological treatments for which there is sufficient evidence to explore the efficacy of these treatments in real world settings and in populations of people with certain pain conditions.

Through extensive and careful planning, NIH is making strides to optimize the benefits of the research resources provided through the HEAL initiative, with the ultimate goal of benefitting the patients. We cannot accomplish this goal alone and appreciate the dedication and tireless efforts of the entire pain research and pain care provider community.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Francis S. Collins". The signature is fluid and cursive, with a long horizontal flourish extending to the right.

Francis S. Collins, M.D., Ph.D.  
Director