A. Specific Aims

An estimated 20% of U.S. adults have low back pain (LBP), with 50-80% reporting a lifetime significant episode and 23% having disabling pain. The costs of LBP exceed $200 billion in the U.S. The opioid epidemic is yet another indication of the significance of this problem, as over 60% of opioid related deaths are chronic pain related and consistent opioid use has been found in 61% of patients with cLBP.The predominant medical model for LBP treatment begins with a patient visit to his or her primary care provider (PCP). Unfortunately, the vast majority of PCP's lack specific training in the examination and treatment of musculoskeletal disorders, such as LBP. Furthermore, commonly used medical therapies, including opioids, spinal fusions and epidurals have either been shown not to be effective or are of questionable benefit and have high-risk profiles. As a result, the 2017 American College of Physicians (ACP) guideline for LBP management strongly recommends patients receive nonpharmacological interventions as a first-line treatment. Included in the ACP guideline are several conservative care recommendations routinely employed by doctors of chiropractic (DCs) and Physical Therapists (PTs). A model for implementation of the ACP guideline that includes DC/PT as Primary Spine Practitioners (PSPs) has been published. This novel model could improve physical function, pain, deviate opioid prescriptions and reduce over-utilization of healthcare services. Further, our previous work suggests that early implementation of PSPs as frontline providers is feasible. However, such real-world models have not yet been widely implemented and even fewer have been validated using rigorous scientific methods. To address this gap, we will borrow from a systems approach to health framework in order to refine and implement a model of care consistent with the ACP guideline for LBP in primary care, using PSPs as the first point of contact. We will then evaluate this model by comparing it to usual medical care in patients suffering from LBP via an efficient cluster-randomized pragmatic clinical trial design that is tightly woven into the NIH Health Care Systems (HCS) Research Collaboratory and involves 3 academic health care systems.

Specific Aims (UG3 Planning Phase)

Finalize 1) the infrastructure required to implement a guideline-based model of care for LBP in 3 academic health centers and 2) a study protocol developed to test this model using a pragmatic, rigorous, multi-site, randomized controlled trial. These efforts will involve completion of XX milestones in 4 categories of phased activities related to completing model development, building implementation infrastructure, finalizing the clinical trial protocol, and transitioning from the UG3 to UH3 phase.

Specific Aims (UH3 Demonstration Phase)

1. **Operationalize the integration of new organizational policies and procedures required to facilitate implementation of a guideline-based model that utilizes DC / PT as the first point of contact for patients suffering from LBP at PCP clinics affiliated with 3 Academic Health Care Systems.**
2. **Determine the comparative effectiveness of a guideline-based model that implements DC / PT as the first point of contact vs usual care for patients suffering from LBP.** The primary outcome is functional status measured using PROMIS and captured at baseline, 12, 26 and 52 weeks. Secondary outcomes include, pain interference, opioid use, and patient satisfaction with symptoms and treatment. *Hypothesis: initial patient contact with DC/PT will improve patient physical function and reduce pain interference compared to usual care.*
3. **Estimate and compare medical resource use and costs of implementing DC / PT as the first point of contact vs usual care for patients suffering from LBP.** Medical resource use will include prescription medications, visits to MDs, DCs, PTs and other types of healthcare professionals, as well as musculoskeletal-related injections, procedures, surgeries, emergency department visits and admissions, and hospitalizations. Standardized unit costs will be assigned to medical resource use and mean direct medical costs per patient will be compared between clinical sites implementing initial point of contact to a DC/PT versus usual care. We also will compute within-trial quality-adjusted life-years to estimate the incremental cost effectiveness initial patient contact with DC/PT versus usual care. *Hypothesis: initial patient contact with DC/PT will reduce total costs as compared to usual care.*
4. **Evaluate patient, provider, system and policy level barriers and facilitators to implementing a new guideline-based DC/PT care model for LBP using a mixed method, process evaluation approach.** Current versus ideal practice for optimal LBP management in primary care will be examined with input at multiple levels using key informant interviews, focus groups, surveys, and documentation review in order improve uptake of clinical guidelines using effective models of care.

IMPACT: This proposal will rigorously test the capacity to move guideline-based LBP care to the forefront of the patient experience within the healthcare system. The results from this study will directly inform implementation and policy efforts to improve the quality of pain management for patients suffering from LBP while simultaneously reducing opioid prescriptions, health care costs and utilization of services.