

**Implementing the National Pain Strategy in an Era of Accountable Care:
Improving Chronic Pain Care in America**

Request for Proposals (RFP)

The American Pain Society and Pfizer Independent Grants for Learning & Change

Release Date: April 12, 2016

I. Background

The American Pain Society (APS) and Pfizer Independent Grants for Learning and Change (IGLC) are collaborating to offer a new funding opportunity focused on improving the care for individuals with chronic pain. It is the intent of this RFP to solicit applications that address the problems and objectives as articulated in the National Pain Strategy (NPS) developed by the Interagency Pain Research Coordinating Committee at the National Institutes of Health.

The APS is dedicated to the science, advocacy, education, and evidence-based multidisciplinary treatment of pain. With a diverse mission that advances treatment of pain from multiple perspectives, APS strongly supports the goals of the National Pain Strategy and is pleased to partner in this funding initiative.

The mission of the Pfizer Independent Grants for Learning and Change is to improve the quality, safety and effectiveness of healthcare through facilitation and support of projects that increase the competence and performance of individual providers and healthcare teams, educate and empower their patients and implement practical solutions within systems-of-care.

The term “independent” means the initiatives funded by Pfizer are the full responsibility of the recipient organization. Pfizer has no influence over any aspect of the initiatives, and only asks for reports about the results and impact of the initiatives which it may share publically.

This RFP is being issued by both organizations. The APS has developed the call for Letters Of Intent (LOI) and will be responsible for review and evaluation of applications. An APS Scientific Review Panel, appointed by the APS, will evaluate scientific merit of proposals and make recommendations for funding to the APS Steering Committee that was responsible for preparing this RFP. Final funding decisions lie with the Steering Committee. Grant funding will be provided by Pfizer. Collectively, \$2 million is available to be apportioned into multiple individual awards.

This RFP model uses a 2-stage process: Stage 1 is the submission of a LOI for review and consideration by the APS Steering Committee. Following Stage 1, a limited number of applicants will be invited to submit a 6-page Full Proposal accompanied by a line-item budget. The Full Proposal format will be provided to those invited to submit. Stage 2 involves the submission of the Full Proposal followed by competitive review by the APS Scientific Review Panel and grant decision-making by the APS Steering Committee.

II. *The Problem*

The Institute of Medicine (IOM) Report “Relieving Pain In America” (2011)¹ clearly articulated the problems facing pain care in the U.S. along with factors that contribute to the provision of quality care and areas of need for improvement in science, education, practice and policy. For example, access to high-quality integrated care based on clinical evidence is hindered by many challenges, including a payment system that does not support optimal care. Even when interdisciplinary care is provided, creating and executing a care plan is often fragmented and hampered by poor communication among clinicians and is often implemented without consideration of patient preferences. High quality research is needed to advance knowledge on the effectiveness of pain interventions, integrated care, models of care delivery, and reimbursement innovations. Also needed are more effective methods of disseminating research findings along with incentives to incorporate such findings into clinical practice. Patient-reported outcomes are rarely collected outside of clinical trials and observational data and registry studies often lack detail and the relevant outcomes to assess critical questions. There is a need to increase the rate of drug discovery and to raise the level of evidence for all forms of treatment used in the management of chronic pain. Despite the need for further research to advance pain science, there exists a strong need to accelerate the adoption of *existing* evidence-based pain management approaches into clinical practice so as to provide better chronic pain management.

The National Pain Strategy (NPS) was developed to articulate objectives in response to the gaps in knowledge and practice identified in the IOM report. The gaps identified within the National Pain Strategy act as the focus for topics associated with this request for proposals.

The National Pain Strategy endorses a population-based, disease management²⁶ approach to pain care that is delivered by integrated, interdisciplinary, patient-centered teams. It is believed that in order to succeed, the current model of care must shift from a fragmented fee-for-service approach to one based on better incentives for prevention (primary, secondary, and tertiary) and for collaborative care along the continuum of the pain experience—from acute to chronic pain across the lifespan, including at the end of life—at all levels of care and in all settings. The goal of coordinated care is to ensure that patients, especially the chronically ill, get the right care at the right time, while avoiding unnecessary duplication of services and preventing medical errors.

Institute of Medicine: *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research*. Washington (DC), The National Academies Collection: Reports funded by National Institutes of Health, 2011

In order to achieve the vision of care described above, the National Pain Strategy is organized around six discrete domains and emphasizes that attention to each domain is important. These domains are the following:

- population research
- prevention and care
- disparities
- service delivery and reimbursement
- professional education and training
- public education and communication

Within each domain, the National Pain Strategy labels the problem, objectives, and strategic goals that will need to be addressed in order to achieve the national transformation in pain prevention and care envisioned by the authors of the Strategy.

III. Purpose

The purpose of this RFP is to encourage submission of LOIs describing projects designed to address the problems and objectives identified in the National Pain Strategy. Successful applicants will clearly link their proposed aims to the National Pain Strategy, describe an approach that employs rigorous methods as appropriate to address their aims, and clarify how their aims and approach can contribute to improved care for individuals with chronic pain.

IV. Types of Proposals to be Considered

This RFP seeks to fund quality improvement, clinical science and implementation science projects that do the following:

- (a) Translate scientific knowledge into clinically useful approaches that improve the care of individuals with chronic pain and that
- (b) Achieve that translation in service of addressing one or more problems and objectives identified within the National Pain Strategy six working groups listed below:

Professional Education and Training

The problem: curricula for health care professionals lack adequate materials on pain assessment, prevention, and treatment. Despite the significant responsibility that health care professionals have for chronic pain patients, many health professionals, including primary care physicians who treat the majority of patients with chronic pain, are inadequately prepared and require greater knowledge and skills to appropriately evaluate the patient, assess the likely neurobiological and psychosocial factors contributing to the patient's experience, and to select the pharmacologic and non-pharmacologic treatments that are most likely to benefit the patient. These are necessary for healthcare professionals to be able to contribute to the cultural transformation in the perception and treatment of people with pain.

Public Education and Communication

The problem: Education is a central part of the necessary cultural transformation of the approach to chronic pain. High quality, evidence based education programs for patients and the public that are designed to promote a transformation in their expectations, beliefs, and understanding about chronic pain, its consequences, its management, and its prevention are needed to make the transformation.

Disparities

The problem: Cultural perspectives influence reports of pain in general and within specific racial/ethnic groups. Available data substantiate under-treatment and inappropriate treatment of chronic pain among racial and ethnic minorities, those with mental health problems, and those perceived as inappropriately seeking drug prescriptions, for a wide range of settings, illness, or injury. These disparities also are seen for women versus men and in different socio-economic strata.

Prevention and Care

The problem: Chronic pain may begin with an injury, or procedure that evolves into a persistent painful condition. Often, however, the cause of its onset is uncertain, and the mechanisms by which it persists are complex. There is a great need to better understand the factors that cause pain to become persistent and to develop and apply measures to prevent acute pain from transitioning to a chronic state. While there is much more to be learned about chronic pain prevention and treatment, existing knowledge could be used more effectively to reduce substantially the numbers of people who suffer unnecessarily. A robust basic, translational, and health services research effort is needed to validate the effectiveness of pain prevention and management strategies already in use, and to develop new ones

Service Delivery and Payment

The problem: Access to high-quality integrated care based on clinical evidence is hindered by many challenges, including a payment system that does not support optimal care. Pain management often is limited to pharmacological treatment offered by a single primary care practitioner or to procedure-oriented and incentivized specialty care that is not coordinated and not aligned with the best available evidence or expected outcomes. This situation is especially relevant for people with high-impact chronic pain, where integrated care is likely to be most effective. More quality research is needed on the effectiveness of pain interventions, integrated care, models of care delivery, and reimbursement innovations. Also needed are more effective methods to disseminate research findings and incentives to incorporate them into clinical practice.

Population Research

The problem: Improvements in state and national data are needed to (1) monitor changes in the incidence and prevalence of acute and chronic pain; (2) document rates of treatment or under-treatment of pain and restrictions to treatment options; (3) assess the health and

societal consequences of pain; and (4) evaluate the impact of related changes in public policy, payment, and care.

V. RFP Key Information

Total Awards	A total of \$2.0M is available to fund multiple grants associated with the RFP. For example, a grant request of \$500K would cover 1-2 years of work depending upon the scope of work proposed.
Specific area of interest	Improving Chronic Pain Care by addressing “gaps” identified in the National Pain Strategy
Geographic scope	The geographic priority and primary focus of this RFP is the United States only.
Eligible applicants	Eligible organizations include, but are not limited to, primary care professional associations (Physician, PA and NP), academic medical centers, health care systems or other inter-professional organizations.
Selection criteria	Submissions will be evaluated on the basis of the following: <ul style="list-style-type: none"> • Alignment to the RFP described area of interest (e.g., National Pain Strategy) • Scientific soundness of plan • Applicant knowledge of and experience with the area • Capability of carrying out the work • Collaboration if appropriate • Potential impact and expected outcomes of the project • Dissemination strategies
Key Dates/deadlines	<ul style="list-style-type: none"> • 04-12-16: RFP released • 06-13-16: Letters of intent due • Week of 07-18-16: LOI applicants notified via email; subset invited to submit full proposal • 09-12-16: Full proposals due • Week of 11-21-16: Notification of funding decisions via email • Grants distributed following execution of fully signed Letter of Agreement • 01-01-17: funded projects start • Individual projects can be funded for up to a maximum of 24-months’ duration
How to submit your LOI	Please go to the website at www.pfizer.com/independentgrants and click on the button “Go to the Grant System”. Registered users should select the LOI link under Track 1-Learning & Change.

	<p>If this is your first time visiting this site you will be prompted to take the Eligibility Quiz. Please be sure to identify yourself as a first-time user.</p> <p>Select the following Area of Interest: IMPROVING CHRONIC PAIN CARE</p> <p>Requirements for submission: Complete all required sections of the online application and upload the LOI (see LOI guidance below)</p> <p>If you encounter any technical difficulties with the website, please click the “Need Support?” link at the bottom of the page.</p>
<p>Questions:</p>	<p>If you have questions regarding this RFP, please direct them in writing to the Grant Officer Robert E. Kristofco at Robert.kristofco@pfizer.com, with the subject line “Improving Chronic Pain Care RFP.”</p>

VI. LOI Guidance

LOIs should be single-spaced using Calibri 12-point font and 1-inch margins. Note there is a 3-page limit (not including references). LOIs should include the following sections.

Main Section (not to exceed 3 pages):

- A. Project Title.
- B. Goal. Briefly state the overall goal of the project. Also describe how this goal aligns with the focus of the RFP and the NPS and the goals of the applicant organization(s).
- C. Objectives. List the *overall* objectives you plan to meet with your project in terms of expected outcomes.
- D. Describe the primary audience(s) targeted for this project. Also indicate whom you believe will directly benefit from the project outcomes. Describe the overall population size as well as the size of your target population.
- H. Project Design and Methods. Describe the design and approach to implementing the project/study.
- I. Innovation. Explain what measures you have taken to assure that this project idea is original and does not duplicate other projects or materials already developed. Describe how this project builds upon

existing work, pilot projects, or ongoing projects developed either by you or other institutions related to this project.

- J. Design of Outcomes Evaluation. Describe the plan for measuring outcomes, including data sources, data collection, and data analysis. Discuss plan for establishing project impact and dissemination of findings.
- K. Describe the attributes of the institutions/organizations/associations that will facilitate and support the execution of the project and the individual leadership of the proposed project. Note: Letters of support from partner organizations will be required at the Full Proposal stage only and should not be included with the LOI.
- L. Anticipated Project Timeline
- M. Requested Grant Amount. The total amount requested is the only information needed for the LOI stage. A full detailed budget is not required. The amount requested can be adjusted at the Full Proposal stage as needed. The budget amount requested must be in U.S. dollars (USD). While estimating your total budget please keep the following items in mind:
 - 1. Institutional overhead and indirect costs must be included within the grant request.
Additional project expenses may include such costs for publication, IRB / IEC review fees, software license fees, and travel. The maximum allowed overhead rate is 28%.
 - 2. Grants awarded cannot be used to purchase therapeutic agents (prescription or non-prescription).
 - 3. Funding may not be used for equipment greater than \$5,000.
 - 4. The maximum allowable total budget request (direct AND indirect costs) for an application is \$750K for the entire budget period.
- N. Additional Information. If there is any additional information you feel the APS Review Panel and Steering Committee should be aware of concerning the importance of this project, please summarize it within the page limitations.
- O. You may include a reference page for citations that **will not** count against the 3 page limit.

All sections should be combined into one document (MS Word or Adobe PDF).

VII. Terms and Conditions

1. This RFP does not commit Pfizer or its partners to award a grant or a grant of any particular size if one is awarded, nor to pay any costs incurred in the preparation of a response to this request.
2. While APS will perform the evaluation of applications, Pfizer reserves the right to reject any or all applications received as a result of this request.
3. For compliance reasons and in fairness to all applicants, all communications about the RFP must come exclusively to Pfizer IGLC. Applicants should not contact other departments within Pfizer regarding this RFP. Failure to comply will disqualify applicants.
4. Consistent with its commitment to openness and transparency, Pfizer reports education grants provided to medical, scientific, and patient organizations in the United States. Pfizer reserves the right to announce the details of successful grant application(s) by whatever means insures transparency, such as on the Pfizer website, in presentations, and/or in other public media. In the case of this RFP, a list of all LOIs selected to move forward may be publicly disclosed. In addition, all approved full proposals, as well as all resulting materials (e.g., status updates, outcomes reports, etc.) may be posted on the IGLC website and/or any other Pfizer document or site.
5. Pfizer reserves the right to share with organizations that may be interested in contacting you for further information (e.g., possible collaborations) the title of your proposed project and the name, address, telephone number, and e-mail address of the applicant from the requesting organization.
6. To comply with 42 U.S.C. § 1320a-7h and 42 C.F.R. §§ 403.900-.914 (the Sunshine Act), Provider (sponsor) must provide to Pfizer specific information for the U.S.-licensed physicians and U.S. teaching hospitals (“Covered Recipients,” as defined by applicable law) to whom the Provider (sponsor) furnished payments or other transfers of value from the original independent grant awarded by Pfizer. Those payments or transfers-of-value include compensation, reimbursement for expenses, and meals provided to faculty (planners, speakers, investigators, project leads, etc.) and “items of value” (items that possess a discernible value on the open market, such as textbooks) provided to faculty and participants, if those faculty and/or participants meet the definition of Covered Recipient. Provider (sponsor) must submit the required information during the reconciliation process or earlier, upon Pfizer’s request, so Pfizer can meet Sunshine Act reporting commitments. Be advised Pfizer will not make any payments to any individuals; grant funding shall be paid directly to Provider (sponsor).

Frequently Asked Questions related to IGLC’s Sunshine Act Reporting Requirements are available on our website http://www.pfizer.com/files/IGLCsunshineFAQ_updatedJan2016.pdf

7. No portion of a Pfizer independent grant may be used for food and/or beverages for learners and/or participants in any capacity. Provider (sponsor) will be required to certify during the reconciliation process and/or the periodic collection of Sunshine reporting that funds were not used for food and/or beverages for learners and/or participants.
8. In the performance of all activities related to an independent grant, the Provider (sponsor) and all participants must comply with all applicable Global Trade Control Laws. "Global Trade Control Laws" include, but are not limited to, U.S. Export Administration Regulations; the International Traffic in Arms Regulations; EU export controls on dual-use goods and technology; Financial Sanctions Laws and Restrictive Measures imposed within the framework of the CFSP - Treaty on European Union; and the economic sanctions rules and regulations administered by the U.S. Treasury Department's Office of Foreign Assets Control.
9. For all Dissemination and Implementation research projects the institution(s) must agree to assume all responsibilities as sponsor of the study as outlined in the proposal, which includes:
 - Obtaining institutional review board (IRB)/independent ethics committee (IEC) approval for studies involving human subjects or human tissue and obtaining a subsequent renewal of this approval as required by local regulations (e.g., yearly, biannually, etc.). In addition, obtaining any IRB/IEC approval for amendments to protocol as they pertain to the research.
 - Obtaining all required personal data privacy or informed consent documentation (as appropriate).
 - Obtaining all required regulatory approval(s) per local regulations.
 - Assuming all reporting obligations to local regulatory authorities.
 - A statement that the research will be conducted in compliance with relevant provisions of the International Conference on Harmonisation, Good Clinical Practice, or Good Pharmacoepidemiology Practice guidelines and all applicable local legal and regulatory Requirements