A. Cover Page

1. Title: Improving functional outcomes and lowering health care costs by enhanced integration of primary care providers and pain medicine physicians for the management of chronic non-cancer pain patients.

Grant ID number: 16026799

Main Collaborators
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2. Abstract

Currently there are more than 100 million patients with chronic pain with less than 4,000 pain medicine specialist (PMS) in the USA, consequently access to these patients in need is deprived. The goal of this study is to demonstrate in a randomized clinical trial that a system of integrated and coordinated care of the chronic non-cancer pain patient by the Primary Care Physician (PCP) or PMS aided by electronic health records will enhance patient's pain functional outcomes, improve health-related quality of life and optimize utilization of the healthcare system. New patients registering at the Rush University Pain Center for chronic low back pain will be informed of the study. Following consent, a determination will be made by the PMS on the best treatment modality in terms of intervention or non-intervention. If it is a non-interventional treatment, patients will be randomized into 2 treatment groups of 100 subjects each: Group1: Subjects will be treated monthly for the next six months by PMS; Group2: Subjects will be treated monthly for the next six months by their own PCP, with a suggested therapeutic plan provided by the PMS. The Primary outcome measure is the Brief Pain Inventory (BPI) short form, a valid measure of the interference of pain with physical functioning. The main objective of the project is to demonstrate that the BPI pain interference measured over six months of subjects with treatment by the PCP is equivalent to those with PMS treatment. Secondary objective is demonstrating lower healthcare costs with PCP.

C. Main Section of the Proposal

3. Overall Goal & Objectives

Goal: To demonstrate that medical care of the chronic non-cancer pain patient (e.g. low back pain) by the Primary Care Provider (PCP), after initial consultation with the Pain Medicine Specialist (PMS), will enhance patient pain functional outcomes, improve health related quality of life and optimize utilization of the healthcare system.

The goal aligns with the focus area of the request for proposal (RFP) from the granting agency, which requires an *evidence-based chronic pain intervention.* Our proposal is a randomized clinical trial to be implemented in our institution, namely the Rush University Pain Center at Rush University Medical Center, Chicago, Illinois.

In addition, the RFP requires that the proposal should demonstrate how the intervention:

1. *Will improve choice and coordination of appropriate treatments*: Our study seeks to demonstrate that choosing a PCP vs. PMS medical care provider for chronic low back pain will not compromise patient functional outcomes. All patients will have an initial consultation with the PMS who will provide a skilled and appropriate pharmacological and/or non-pharmacological therapeutic plan for the treatment of chronic low back pain, irrespective of later selection to management by PCP or PMS.
2. *Enhance patient outcomes*: Our study assesses patient functional outcomes over a 6-month period using standardized, validated scales.
3. *Increase patient satisfaction by reducing pain and by improving function and/or optimization of healthcare utilization*: Patients are expected to have higher satisfaction scores for the same treatment in the PCP than in the PMS group due to their greater familiarity with the PCP. This shift of non-interventional care for the chronic low back pain patient from PMS to PCP will provide optimization of the health care system by greater access to PMS knowledge for patients in chronic pain.
4. *The project goals are consistent with the mission of our institution, Rush University Medical Center, whi*ch is "to provide the very best care for our patients" and "enhancing excellence in patient care for the diverse communities of the Chicago area". Making chronic pain management available from the patient's own PCP is commensurate with the goals of our institution. Extensive use of and integration of electronic health records (EHR) among diverse PCPs is consistent with Rush's goals of diversification of health benefits.

Objectives: There are 4 main objectives. Using a prospective, randomized clinical trial design for patients with *chronic non-structural non-specific low back pain* will:

1. Demonstrate that functional improvement measures over a 6-month period for chronic low back patients under the care of PCP, using a therapeutic plan formulated initially by the PMS, are *equivalent* to those under the care of the PMS only.
2. Show that patients randomized to the PCP group will have fewer pharmacological interactions (e.g. anti-fungal medications with opioids) because the PCP can monitor and optimize the necessary ancillary treatment measures (including hormonal effects of opioids).
3. Patients will have higher satisfaction scores in the PCP group than in the PMS group due to their greater familiarity with the PCP, possibly more total encounter time with the PCP, and generally shorter and more convenient travel.
4. Demonstrate that PCP treatment will reduce healthcare costs by minimizing the time patients spend with specialists (in this case, PMS) while allowing greater access of chronic pain patients to the expertise of a PMS.

Hypothesis: Functional outcome from PCP treatment for chronic low back pain after initial PMS evaluation and therapeutic guidance is equivalent to patients receiving PMS treatment only.

Such a result would be beneficial to both patients and the healthcare system, especially since there are insufficient numbers of PMSs to treat all the chronic pain patient population in USA.

Background to objectives

More than 25% of adults in the USA have had low back pain in the last 3 months; this number increases to 55% over 12 months.[1] *Low back pain is the second most common reason for visits to physicians*, and despite increased resources, complex management of low back pain results in incremental healthcare expenditures. The economic burden of low back pain in the USA has been estimated to range from $84 billion to $624 billion, with the major contributor to this high cost being that of medical care.[1]

There are 100 million chronic pain patients and only 3-4,000 pain medicine physicians in USA

This project will meet the goal of the specific area of interest for the RFP by demonstrating in the low back pain population that it is feasible to shift the care of non-cancer chronic pain patients to the Primary Care setting, where there are many more providers, from the PMS, where far fewer currently exist. This will require integration and coordination so that the expertise of the PMS is made readily available to the PCP, partially through the aid of an EHR. The result of this collaboration will be to achieve similar levels of improvement in health-related quality of life in patients managed by the PCP as would be by the PMS, while at the same time lowering healthcare costs. The estimated 100 million chronic pain patients in the USA[2] having follow-up visits with their PCP, rather than a PMS, would lead to a considerable saving in both time and cost.

4. Technical Approach

In this trial, each chronic low back pain patient presenting to the Rush University Pain Center will initially be evaluated by the PMS. If no interventional pain therapy is required, a multimodal therapeutic plan (pharmacological and/or non-pharmacological) will be formulated to manage the chronic low back pain. A complete workup will be performed to accomplish this task (see below). Patients meeting criteria would then be randomized and followed by either a PMS or PCP for continued treatment over the next 6 months. This initial multimodal therapeutic treatment can be altered by the respective treatment groups (PMS or PCP) to which study subject has been randomized. EHR will be utilized by both the PMS and PCP.

a. Current Assessment of need in target area

In the USA, there is a shortage of physicians specializing in chronic pain management. In fact, one of the limitations to appropriate care for non-cancer chronic pain patients, according to the 2011 Institute of Medicine (IOM) report, is the small number of PMSs in practice, estimated to be only ***3,000 - 4,000 in the entire USA***.[2] The implication is that PCPs, though not having specific expertise on chronic pain management, are required by necessity to treat most chronic pain patients with little guidance on effective care. This includes the use of opioids. It is well known that there is an epidemic of opioid drug abuse, and the most common prescriber of opioids in the USA is the PCP.[3] Despite the need for PCPs to be competent for managing chronic pain, pain management receives little emphasis in medical professional education programs. In USA medical schools, students only receive an average of 11 hours of education on pain.[4] Inadequate education of health care professionals is a major and persistent barrier to safe and effective pain management.

Pain is one of the most common symptoms for which patients seek the help of healthcare professionals. With our increasing aging population, the number of patients with chronic pain will escalate and this will place a tremendous strain on the already overburdened healthcare system. Many PCPs are reluctant to prescribe opioids for non-cancer pain,[5] even though they are one of most efficacious medications for moderate to severe pain. One of the major concerns in using opioids for non-cancer chronic pain is opioid abuse. In addition, chronic opioid therapy leads to tolerance, dose escalation and various neuroendocrine physiological changes.[6] The concerns of the PCP in opioid prescription relate to the appropriateness, abuse of prescriptions, addiction, tolerance, drug interactions, and possible medical litigation.[5,7] It is important to recognize that the PMS has similar concerns as the PCP in regard to opioid therapy and its legal ramifications.[5]

Urine toxicology screening in not very common among PCPs prescribing opioids, with 93% reporting they do not do screening before starting opioids on new patients being treated for chronic pain.[7] In addition, 85% of PCPs do not perform toxicology screens once or twice a year on established chronic pain patients receiving opiods.[7] Therefore, urine toxicology testing is underutilized in the primary care setting.

The PMS expertise on multimodal therapy for chronic pain, including pharmacological, non-pharmacological and interventional approaches, will enable the PMS to formulate the best strategy for the treatment of chronic non-cancer patients. ***Integration of the PMS and the PCP***

into a collaborative treatment protocol for the patient could relieve the strain on the health care system by allowing a larger share of chronic pain patients to be managed by the PCP.

With our aging and increasing population, collaboration between the PCP and PMS will relieve the strain on the health care system that exists because *"there are more than 33,000 patients with chronic pain for every PMS in the USA"*.[2]

Risk Mitigation Strategies for opioid therapy. To ameliorate concerns with opioid use, opioid agreements (or contracts) have been developed that ensure that the chronic pain patient only obtains potent narcotics from one prescribing provider.[9] The use of opioid contracts is becoming increasingly popular in PCP offices.[5,7,8] A recent study reported a 60 percent adherence rate to the contract with a median follow-up time of 2 years.[9] These agreements are signed contracts between the PCP and the chronic pain patient.

Random urine drug testing is an essential part of the contract. A urine drug screen is used to detect illegal and certain prescription drugs in the urine. Such screening can indicate either illicit drug use or diversion of prescribed drugs intended for patient use. Although there are ethical considerations for PCPs in using urine drug screening, it is critical for the effective management of chronic pain.[10]

Affordable Care Act. The Patient Protection and Affordable Care Act of 2010 specifically mandated a 2011 IOM meeting to improve the delivery of evidence based care for pain management. One of the main recommendations of the 2011 IOM report was to "support collaboration between PMS and PCP".[2] The intention of our proposal is to accomplish that objective in a clinical trial with detailed methodology that can be replicated and sustained over time. Having the PMS provide an initial evaluation and algorithm to the PCP will give a baseline assessment and guidance, including risk stratification, for opioid therapy to the PCP.

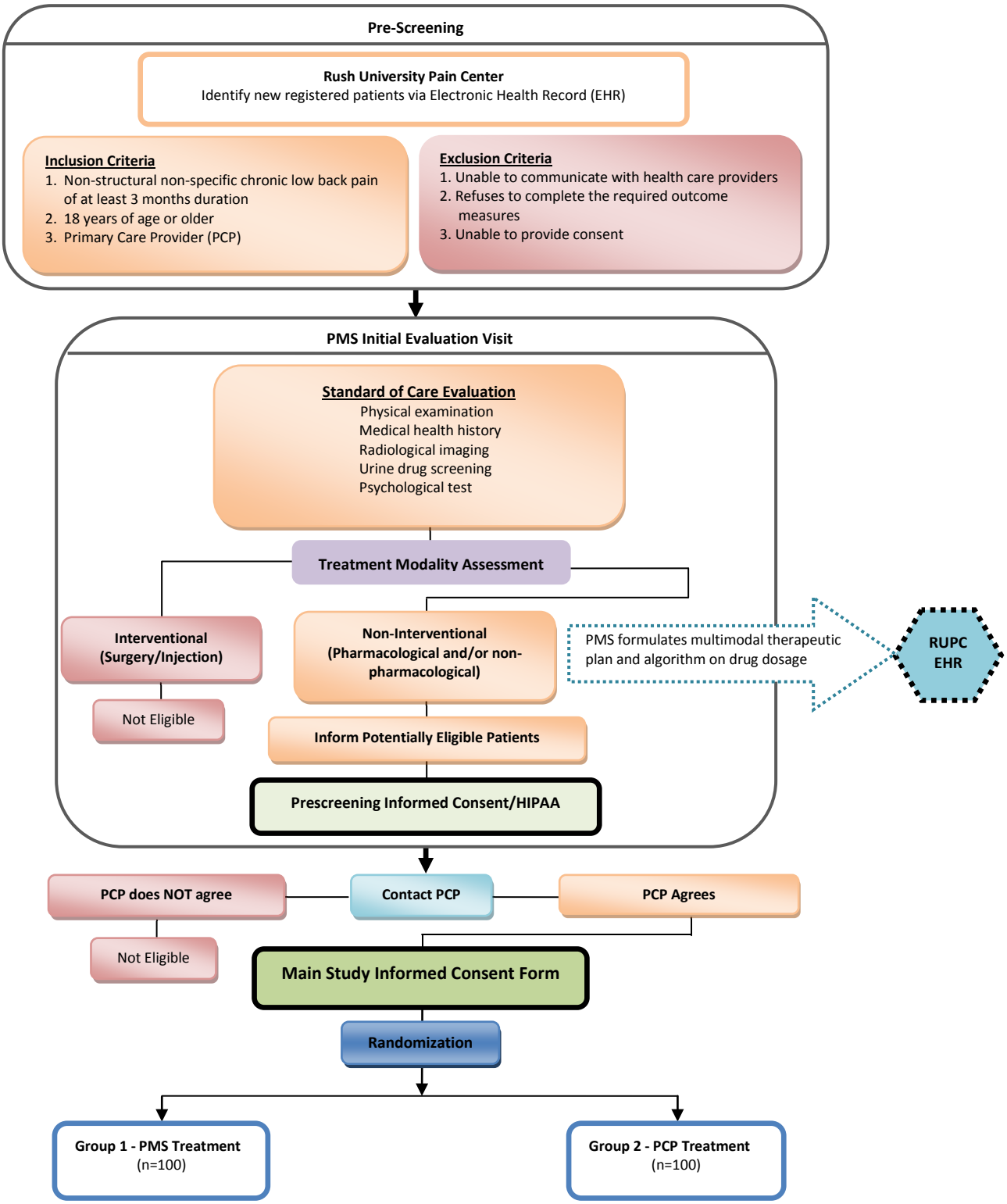
b. Project Design and Methods

This project is a prospective, randomized clinical trial of patients with non-structural non-specific chronic low back pain who present to the pain center. *An initial evaluation and treatment plan will be formulated by the PMS for all patients*.

Group 1: Subjects will be treated monthly for the following 6 months by PMS at the Rush University Pain Center.
Group 2: Subjects will be treated by their own PCP for monthly visits for 6 months.

Prior to starting the clinical trial, approval will be obtained from the Rush University Medical Center IRB. The clinical trial was submitted to the IRB on October 6, 2014 and is currently pending review and approval (ORA#14100602). New adult patients registering at the Rush University Pain Center at Chicago, IL for chronic low back pain conditions will be considered for the study. Our criteria for chronic low back pain evaluation and treatment is similar to current standards.[11,12] We will only include patients that have a PCP for consideration in the study (almost all patients coming to rush pain center have a PCP). Although the Rush University Pain

Center also sees patients with neck pain, fibromyalgia, and peripheral neuropathy, low back pain is the most prevalent, and ***choosing one diagnosis for the study will reduce variability in outcome measures.*** The initial evaluation visit, as part of the routine care for all new low back patients, will include the following: a full physical examination, review of medical health and medication history, and radiological imaging (EHR will be used for the study). In addition, all new patients will need to provide a urine drug screening test and will need to undergo psychological testing and evaluation.



Inclusion Criteria

1. Non-structural non-specific chronic low back pain of a least 3 months duration
2. 18 years of age or older
3. Has a primary care provider (PCP)

Exclusion criteria

1. Unable to communicate with health care providers
2. Refuses to complete the required outcome measures
3. Unable to provide consent

A determination will be made by the PMS on whether the best treatment modality includes an interventional approach or non-interventional. If a non-interventional treatment (pharmacological and non-pharmacological) is selected, that can be implemented by a PCP, the patients will be informed of the study, and if interested, a Prescreening Informed Consent and HIPAA form will be obtained from patient to give permission to contact their PCP. At that point, the patients' PCPs will be contacted, presented with the study information, and asked if they want to participate in the study. If the PCP agrees, the Main Study Informed Consent will be obtained from the patient.

PMS initial evaluation and treatment

After evaluation, 200 consented subjects (with cooperating PCPs) will be randomized into one of the two treatment groups (n=100 per group). The patient population will be identical for both groups and due to randomization, co-morbidities should be similar in both arms of the study. If there are imbalances in co-morbidities between the study arms after study completion then these co-morbidities will be factored into the final model for the statistical analysis. Subjects in both groups will undergo the following:

1. Urine drug screening test (qualitative); includes amphetamines, barbiturates, benzodiazepines, cannabinoids, cocaine, ethanol, and opioids
2. Receive a sample copy of an opioid contract/agreement, with explanation (sample contract for PMS and PCP in Appendix)
3. PMS will query the Illinois prescription monitoring program for that patient to determine the various health care providers who are prescribing narcotics or other controlled medications.
4. Undergo a psychological test and evaluation by the Rush University Pain Center **psychologist** (including the Screener and Opioid Assessment for Patients with Pain–Revised (SOAPP–R)[13]), to determine risk of drug abuse.

Results of these evaluations will be provided to PMS or PCP, depending on randomization.

Group 1 (PMS treatment): Subjects will continue to be followed for the next 6 months by the PMS (typically every month for the treatment of chronic pain) per standard protocol. The PCP will not be involved in the treatment.

Group 2 (PCP treatment): Subjects will be followed by the PCP for the next 6 months. The PCP will be involved using EHR and a multimodal therapeutic strategy will be communicated to the PCP by the PMS. The PCP will make dosage based on an algorithm provided by the PMS on how to adjust drug doses over time (general template—See below). In addition, a direct line of

communication will be set up between the PCP and the data integration clinical coordinator to handle serious medical concerns. In case of serious medical events, the subject will be withdrawn from the study and appropriate medical care will be provided by the PMS or PCP.

Opioid contract: For subjects in the PCP treatment group, a medication contract agreement outlining patient and provider responsibilities will be used and random drug testing will be made between the patient and the PCP.[8] PCPs will be informed of the contract agreement at the time that they are asked to participate in the study. The purpose of the medication contract agreement is to establish an expected code of conduct and prevent misunderstanding about certain pain medication the patient will be prescribed for management of chronic pain. The contract agreement monitors patient's adherence, and helps check that patients are compliant with the medications ordered in order to facilitate care, and improve communication between doctor and patient. The agreement requires patients to: undergo random urine drug tests (which are *quantitative*); request refill of prescription only at the time of the office visit or during regular office hours; bring medication containers for each visit; refuse to accept pain medication from any other health care provider; safeguard medication from loss, theft, or use by others; return unused medication to the pharmacy in case of changed medication or dosage. The patient agrees to communicate fully with the doctor about details of pain, effect of pain on daily life, and input on how well the medication is helping to decrease the pain and increase functionality and activities of daily living. The contract includes patient's acknowledgement that the goal of treatment is to decrease pain and improve quality of care, and that medication may be tapered or discontinued based on the physician's discretion. For subjects in the PMS treatment group, the same medication contract agreement as in the PCP treatment group will be made between the subject and the PMS, as is the standard practice at the Rush University Pain Center.

Violations of the opioid contract for subjects in either group will be managed according to their respective health care provider's discretion. If there is concern of serious drug interaction or use of recreational illicit substances, the subjects will be withdrawn from the study.

It will be the responsibility of the ***project manager*** to ensure that the Project Methods are being carried out in a correct and timely manner.

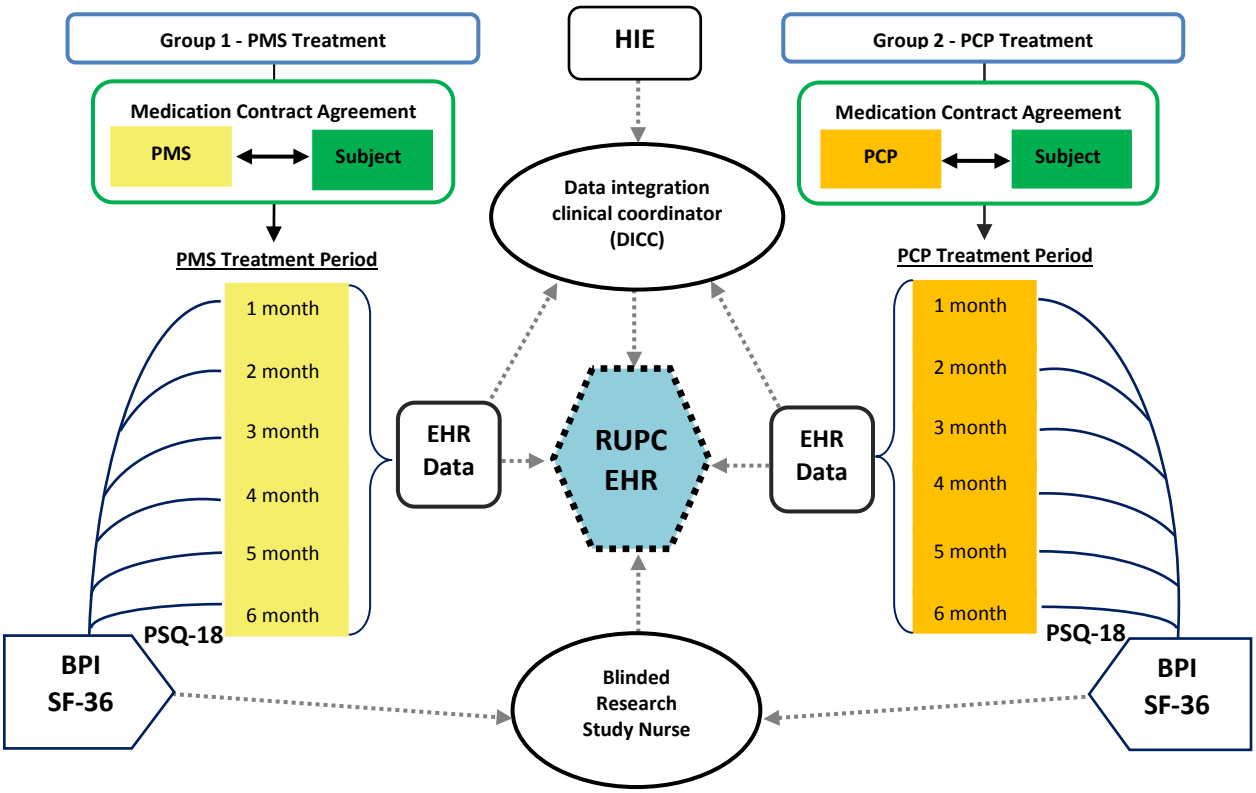
Template for treatment of low back pain to be provided for PCP.
This template is only a suggestion, and clinical and medical judgment for each patient will be decided by the PMS. Listed are the categories of pharmacological and non-pharmacological modalities,[11,12] but the PMS will formulate a <u>patient-specific prescriptive plan</u> after evaluation at the initial work-up:

1. Non-steroidal anti-inflammatory drugs (NSAIDs): preferably COX-2 inhibitor for all patients. If NSAIDs are prescribed, GI prophylaxis needs to be provided.[14,15] This would be prescribed to all patients and will be provided daily and not 'as needed' medication, unless there are adverse events that prevent its administration.
2. Muscle relaxants: such pharmacological agents include baclofen, tizanidine, or lorazepam to relieve painful muscle spasms[16]

3. Opioids: long-acting opioids (oxycodone, controlled- release), short-acting opioids (e.g. hydrocodone/acetaminophen)[14,15,17]
4. Anticonvulsants: mainly gabapentin or pregabalin[18]
5. Transcutaneous electrical nerve stimulation (TENS) unit[19]

At the end of the 6-month treatment period (end of study), patients will be given the option to continue the treatment with their group or changing to any other treatment available.

c. Evaluation Design



Outcomes

The Primary outcome, 'Pain interference with daily activity', is obtained from the Brief Pain Inventory (BPI) short form, a reliable and valid measure of the interference of pain with physical functioning.[20,21] The BPI is a self-report questionnaire using items (questions) on a 11-point scale (0-10), and will be used to assess impact of pain on daily activities, and pain severity, over the 6 month treatment study period. The BPI can be factored into two subscales: functional interference and pain intensity. For the Primary outcome we will use the functional interference subscale, which consists of 7 items (questions) under the heading of 'Pain interference with daily activity over the last week', and use the *mean value of the 7 responses*; as a secondary measure, the 4-item pain intensity subscale, will be used.

A ***research study nurse***, blinded to group allocation, will call patients (from both groups) every month to collect BPI questionnaire responses over the phone. In addition, a general measure of functional health and well-being, the *SF-36 health-related quality of life* outcome measure

(Short-Form 36 Health Survey), will be collected during the same call.[21] The SF-36 total score can be used as an overall health measure, or as a measure of two different health domains: physical health (including bodily pain) and mental health, as well as further division into more specific subscales. A baseline BPI and SF-36 will be obtained from each subject's initial visit record (EHR). The research study nurse will enter data obtained from the phone calls directly into the Rush University Pain Centers (RUPC) EHR on the eClinicalWorks platform.

To evaluate "patient experience of care", a reliable and validated tool, the *Patient Satisfaction Questionnaire (PSQ-18)* will be given at discharge on the initial PMS visit and at the completion of study.[22] The PSQ-18 assesses global satisfaction with medical care as well as satisfaction with six aspects of care: technical quality, interpersonal manner, communication, financial aspects of care, time spent with doctor, and accessibility of care.

To evaluate procedural variations, side effects and secondary outcomes over the 6 month follow-up treatment period, a ***data integration clinical coordinator (DICC)***, not blinded to group allocation, will query electronic and physical health records, from both the PCP and PMS, as well as corresponding HIS's. The DICC will coordinate the multiple data sources and consolidate this information into the RUPC EHR. All data input will be audited with reference to original source(s) and securely transmitted at the highest level of interoperability available (i.e. semantic interoperability in HL7 format) with coordination of the statistician and eClinicalWorks support team. Active filters will be created to facilitate variable matching to access data from systems that do not have a high level of interoperability by the statistician. Data that cannot be directly imported or algorithmically transcribed into the RUPC EHR will be entered manually by the DICC. The statistician will perform monthly validation on data input from all sources.

In addition to managing EHR import, the **DICC** will record procedural outcomes: number of adverse drug reactions (directly attributable to multimodal therapy), number of adverse pharmacological interactions (analgesic drugs with other medications, e.g. for hypertension or diabetes); cost ($) of care; number of visits to pain specialist and number of visits to primary care provider; patient compliance with medication use; medication dosing and treatment variation, patient dropouts in study; and percentage that failed random urine drug screening.

At the completion of the study period the PCP will be queried on how satisfied they were with the patient's treatments and overall satisfaction with the process using a simple 11-point NRS scale (0-10) for satisfaction with patient treatment, satisfaction with the data transfer implementation, and overall satisfaction with the process.

Electronic Health Records (EHR):

The RUPC EHR was specifically developed to track and record the pain population, with specific modules created by this investigative team to record pertinent health and outcome information. All EHR data will be securely entered or transferred into the Rush University Pain Centers eClinicalWorks EHR (RUPC EHR) from multiple providers using several data exchange/integration modalities. The RUPC EHR is built on the eClinicalWorks V10 platform, which is an ONC-HIT 2014 Complete EHR Certified, ICD-10 compliant EHR and supports both Stage 1 and 2 meaningful use measures. RUPC EHR data is stored on eClinicalWorks as a cloud

service with full access to data at the item level. We have the full support of eClinicalWorks to assist with data integration as well as support with any additional custom data entry modules.

EHR interoperability:

Since EHR vendors/software and even specific EHR implementations can vary greatly among PCPs, integration and cross-software data compatibility is a challenge, but the methodology outlined below will allow us to integrate even disparate data as well as evaluate the interoperability among systems.

For each EHR data source (PCP EHR, HIS) a transfer method to the RUPC EHR will be constructed with different methods and tools used depending on level of health information interoperability (1. Foundational, 2. Structural, 3. Semantic). Higher levels of interoperability provides higher quality data with more homogeneity, with lower levels requiring more transformation and produces less compatible data streams. Individual data sources will determine interoperability levels and consequently our communication methods.

There are two main structure of data interoperability, Peer-to-peer (i.e. PCP EHR → RUPC EHR) or an Health Information Exchange (i.e. PCP EHR → HIE → RUPC EHR). We are currently implementing both methods from several different sources and have other sources planned:

Provider-to-provider data transfer (P2P): Connectivity between the PCP EHR and our RUPC EHR uses an eClinicalWorks custom solution for gathering medical records/data from private practices; P2POpen. P2POpen is an EHR independent network that allows the secure transfers of EHR data from practice-to-practice, provider-to-provider and peer-to-peer. It will allow any provider to communicate with the RUPC EHR using encrypted file transfer protocols. For those PCPs without interoperable EHRs, or who do not wish to use P2POpen, we use direct encrypted file transport protocols to send digitized medical records manually from the PCP.

Corporate health information exchanges (HIE): Another option we have for our patients from larger practice settings is eClinicalWorks Electronic Health eXchange (eEHX®), which facilitates interoperability between clinical systems among hospitals enterprise customers and community-wide projects.

Governmental Health Information Exchange (HIE): The majority of patients seen by the Rush university pain center come from the Chicagoland area and neighboring Indiana communities. Both Illinois and Indiana have health information exchanges (ILHIE, IHIE respectively). Indiana has DOCS4DOCS service and the Indiana Network for Patient Care (INPC) while Illinois has ILHIE Connect (EHR retrieval service) and ILHIE Direct (secure messaging solution). The systems are structured differently and have different capabilities but we have structured plans to integrate the available data from all these sources to provide a comprehensive understanding of our patient's medical history and current status.

Using either P2P or one of the standardized information exchanges provides a wide array of data integration possibilities. If there is no direct electronic transfer protocol for the PCP EHR or HIS at the time and a conversion script cannot be created, then the DICC will import the data from the remote EHR or HIS manually. Implementing and managing the data transfer and

integration processes will be the department's network specialist (Sean Yang) and biostatistician (Mario Moric).

EHR Data validation:

The data integration clinical coordinator (DICC) will update the RUPC EHR using two different methodologies, EHR transfer/integration or transcription. For the EHR transfer method, data will be exported/transferred from the PCP EHR to the RUPC EHR using a variety of secure digital transfer systems (HIS, EHR-EHR via translation interface, VPN, etc.) and using the methods previously mentioned based on the respective systems interoperability. For the transcription method, at monthly intervals any paper data still used by the PCP will be faxed and then transcribed into the RUPC EHR. These two parallel tracks will be used to evaluate and test consistency across data source formats. Additionally, at the end of the 6 month trial period, the PCP will report details about the treatment, and provide additional documentation or information so that both the patient's reports and the EHR-data transfer information can be verified.

In addition to the transcription data entered and the EHR data transferred by the data integration clinical coordinator, direct entry of clinical data by the Rush research nurse will be automatically entered into the RUPC eClinicalWorks EHR. Data from the Rush research nurse will be used to test the primary outcomes, and the data integration clinical coordinator data will be evaluated for validity to evaluate EHR interoperability of each system/data repository.

Statistics, Sample size: For the power analysis, an estimate of the standard deviation (SD) for our population was derived from a study of the use of an opioid in the treatment of chronic non-cancer pain.[23] Using a SD of 13.8 for the primary outcome (BPI), and assuming no mean difference between the PCP and PMS groups (equivalence) and with a ± 7.0 zone of equivalence (approximately half the SD), at 90% power, requires a sample size of 170 total patients (85 per group). Assuming a 20% drop out rate, we would need approximately 100 patients per group (200 total).

Statistics, Outcome analysis: The primary outcome of 'pain interference' will be quantified by the BPI pain interference subscale taken at least monthly over the 6 month study period. To estimate overall pain interference, each subject's scores over this time period will be used to calculate the area under the curve (AUC) of pain interference for that subject. The Primary outcome (BPI AUC pain interference) for the two treatment groups will be evaluated (Objective 1) using a test of equivalence {Two-One sided T-tests (TOST)}. The secondary outcomes of the BPI pain intensity scores and the SF-36 measure will also be computed in a similar manner and tested by the TOST method. Difference in healthcare costs will be compared between the 2 groups with Student's t-test (Objective 4). Patient satisfaction (PSQ-18) measures at baseline and at each month will be tested for between group differences using a repeated measures general linear model (Objective 3). For all measures, the influence of covariates will be evaluated, and if important, will be compensated for through the use of general linear modeling and then corrected AUC measures will be tested using the TOST method.

The incidence of adverse events, and adverse pharmacological interactions, will be compared between the 2 groups with contingency tables and Pearson chi-squared or Fishers exact test (Objective 2).

Analysis will follow an intent-to-treat protocol, with a sensitivity analysis (comparison with the per-protocol analysis results) to evaluate the effect that dropouts had on the results. SAS statistical software version 9.2 will be used for all analyses. The cut-off for significance will be $\alpha<0.05$ with logically grouped sets of tests adjusted for family-wise error inflation using step-down Bonferroni adjustment.

Quantifying amount of change expected: For BPI and SF-36 we expect to show statistically equivalent scores for the 2 treatment groups over the 6 month treatment period. If the pre-randomization baseline scores are not equivalent between the 2 groups (not anticipated), then we will proceed as with other covariate adjustment methods described under "Statistic, Outcome analysis", with each subjects baseline score entered as a covariate.

Health Care Resource Utilization and Direct Medical Costs: Health care expenditures and direct medical cost will be examined to evaluate use of healthcare resources throughout the study period. We will capture the following measures of pain management related health care utilization for the 6 months: number of outpatient visits including primary care and specialty care visits, hospital inpatient (number of admissions), emergency department visits (number of visits, medications (initial and refills), radiology and imaging procedures related to low back pain. Direct costs associated with each specific medical utilization resource will be compared across all measures. Billed costs for services received will be collected from the PCP and/or PMS for which the service was provided. Monetary values for services obtained will be totaled for each subject and used to evaluate group differences.

For total cost ($) of care we expect to see a 50% reduction in the 6 month pain management costs of the PCP group vs. the PMS group. This is based on the same number of physician follow-up visits for both groups, but with an average expense per office visit of **$145** to see a PCP vs. **$315** to see a PMS (**54% reduction in cost for PCP visit**).[24] If the number of visits to the PCP are less than the number of visits to the PMS over 6 months, then the cost savings would be even greater.

From that AHRQ report,[24] we can extrapolate that if the functional outcomes of the chronic back pain patients over the 6 month period are the same, the cost savings to the health care system from following up with PCP will be $ 2,040 over a year per patient ($170/month). If this is projected for 100 million chronic pain patients, the annual cost savings would be phenomenal.

For the incidence of any adverse drug reaction (directly attributable to multimodal therapy), such as sedation or pruritus with opioids, we do not expect to see a difference in the PCP-managed vs. the PMS-managed groups. However, for the incidence of adverse pharmacological interactions (e.g. anti-fungal drugs with opioids,[25] HIV medications with opioids[25]), as well as hormonal effects of opioids,[6] we anticipate slightly fewer incidents with the PCP management

group (although the study is underpowered to statistically demonstrate this secondary outcome).

To determine if the target audience (subjects with chronic back pain) was fully engaged in the project: The secondary outcome measures of patient compliance with medication use, patient dropouts in the study, and percentage that failed random urine drug screening will allow us to judge if the subjects were fully engaged in the trial. If the PCP managed group had more compliance issues than the PMS group in the interim analyses, then the PCP/PMS therapeutic plan and patient instructions need to be modified. However, we believe that having the opioid agreement for chronic opioid management between the PCP or PMS, and the patient, will keep the PCP group as fully engaged as the PMS group.[7,8]

Plan for project outcomes to be broadly disseminated: The randomized clinical trial will be registered on ClinicalTrials.gov before subject enrollment, and the results published in peer-reviewed journals. In particular, the Principal Investigator (PI) would seek journals (such as JAMA, where he has published before) that have a wide readership in the PCP community. In addition, Dr. Buvanendran (PI) has presented seminars on chronic pain management for the PMS community in the past, and will use these forums to actively disseminate the results of this study among the PMS community, in addition to press releases from the hospital (the PI and Rush University have done this several times). Likewise, our PCP partner in this study is active in meetings that PCPs attend and will use these venues to disseminate the results of this study among the PCP community.

5. Detailed Workplan and Deliverables Schedule

Patients will be recruited over a 15 month period with follow-up for 6 additional months. The final 6-month period will be for data analysis and preparation of publications. The Rush University Pain Center typically evaluates 2 new patients/day with low back pain, and we are confident that at least 50% of these patients can be consented to be enrolled in this study.

Deliverables Schedule

Funding year	**1**	**1**	**1**	**1**	**2**	**2**	**2**	**2**	**3**
Months within each funding year	**1-3**	**4-6**	**7-9**	**10-12**	**1-3**	**4-6**	**7-9**	**10-12**	**1-6**
Final protocol submitted to IRB	x								
EHR protocols, data entry forms	x								
Patient enrollment (after IRB approval)		x	x	x	x	x			
Data collection completed		x	x	x	x	x	x	x	
Interim analysis of objectives completed			x	x	x	x	x	x	
Quality assurance analysis completed			x		x		x	x	
Data cleaning completed				x		x		x	x

Final statistical analysis completed									x
Final report to Pfizer submitted									x
Manuscript submitted									x

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D. Organization Detail

1. Leadership and Organizational Capability: Currently the Rush University Pain Center has over 10,000 patient visits per year, most of whom have a chronic non-cancer pain condition, with spine related (lumbar and cervical) pain being the most frequent. After the initial evaluation, the average patient visits the clinic 6 to 8 times over the next 6 months. Rush University Medical Center is a 674-bed academic medical center.

Rush University Pain Center: The Principal Investigator (PI), Asokumar Buvanendran, MD, is board certified in both Anesthesiology and Pain Medicine, and works in this clinic. Outpatient visits will be at one of the country's largest pain centers, the Rush University Pain Center on the Medical Center campus, providing chronic pain management services. The pain center has a front office and patient check-in area, and administrative offices including an office for the staff psychologist, 9 exam rooms and a conference room. The clinic includes 15 network computer workstations. The clinic also has a computer scheduling and medical information system (e-clinical) that stores patient information, visit information, and data from psychological assessments. We in addition have 3 psycological students who work and are involved in research in chronic pain medicine. In addition we have the capability to do urine toxicology qualitative assay with results in 48 hours confirmed.

Anesthesia Clinical Research Office: This is a 900 square feet area with 5 offices, one of which is fully equipped to perform clinical examination and testing. The PI has an office in this space. The Department of Anesthesiology pays rent for this space. This office is in the Rush University Medical Center (14th floor) and also hosts the biostastician's office and computers, servers, faxes, and printers. It has been in existence at the same location for more than five years.

Interaction with Primary Care Providers: The Rush University Pain Center staff work closely with personnel in internal medicine, family medicine, physical therapy, and occupational therapy. Physicians or health professionals request consultations, referrals, and other information by contacting our clinic. In addition, we have consulted with the Department of Internal Medicine at Rush University Medical Center and will be using their input to plan the details of the primary care provider interaction with the pain management specialist.

2. Staff Capacity:

Asokumar Buvanendran, MD (Principal Investigator)
Department of Anesthesiology
Rush University Medical Center

Role: As the investigation's ***Principal Investigator***, Dr. Buvanendran will bear overall responsibility for the successful implementation, execution, analysis, and reporting of the proposed clinical trial. Responsibilities will include, designing all study forms, guiding the database development, assisting with IRB submissions, managing and overseeing all data collection, assessing all adverse events and protocol deviations, overseeing recruitment, communicating with and preparing reports for the funding agency, overseeing data analysis, overseeing funding/budget issues, and first-authoring resulting manuscripts.

He will be responsible for training, and overseeing research nurse, clinical coordinator (Ms. Christine O'Neil, Dr. Mahendrakumar Shah), and project manager (Karolina Mroczek, MS).

Qualifications: Dr. Buvanendran is a Professor of Anesthesiology, Board-certified in Pain Medicine. He is also a senior Pain Medicine Attending Physician practicing at the Rush University Pain Center, one of the country's largest pain centers, providing chronic pain management services to more than 10,000 patients annually. He has conducted basic and clinical research involving acute and chronic pain management and assessments for 14 years. His national and international reputation in the area of pain management has led to collaborative work with multiple investigations with US and International scientists and he and his research team have been nationally recognized for clinical trials in acute postoperative pain intensity and outcomes. During the course of the last 12 years, he has conducting several large randomized, controlled clinical trials in the field of multimodal analgesia including multicenter studies. Dr. Buvanendran is a board certified pain management physician who has treated both acute and chronic pain patients on a daily basis, for more than 14 years.

Amir K. Jaffer, MD, MBA (Co-Investigator)
Department of Internal Medicine,
Rush University Medical Center

Role: As the investigation's ***Co-Investigator***, Dr. Jaffer will bear overall responsibility for overseeing the PCP role in the proposed clinical trial. Responsibilities will include overseeing PCP sites, designing all study forms, guiding the database development, assisting with IRB submissions, managing and overseeing all data collection, assessing all adverse events and protocol deviations, and overseeing recruitment.

Qualifications: Dr. Jaffer is Professor and Senior Vice Chair for Medical Affairs of the Department of Internal Medicine at Rush University Medical Center.

Karolina Mroczek, MS *(Project Manager),* Department of Anesthesiology
Rush University Medical Center

Role: Ms. Mroczek as the research administrator for the Department of Anesthesiology at Rush University Medical Center, will provide daily support to the principal investigator in the administrative management of the study, including ensuring that data entry and data validation are complete. She will assist the investigator in his administrative responsibilities.

Qualifications: Ms. Mroczek has over 4 years working as a clinical research coordinator and IRB administrator. She has extensive experience with clinical trials, documented training in the protection of human subjects and the ethical conduct of human subjects research, and training in and understanding of good clinical practice.

Mario Moric, MS (Biostatistician), Department of Anesthesiology
Rush University Medical Center

Role: Biostatistician, Mr. Moric he will oversee the statistical design, statistical programming, data integrity and analysis, data management and EHR sharing plans, and database design and maintenance, and reporting of the data to the Principal Investigator.

Qualifications: Mr. Moric has greater than 13 years of experience in designing, conducting and analyzing clinical trials. His work at Rush University Medical Center in anesthesiology and orthopedic surgery has included design and analysis of numerous clinical trials, including multiple pilot and clinical trial studies with the Primary Investigator of the proposed trial. His statistical expertise and interests include design of experiments, group sequential and adaptive trial design and analysis, methods for analyzing a composite of multiple binary outcomes, survival analysis, mixed effects modeling, generalized estimating equation analysis, agreement/reliability studies, causal effects and potential outcomes, bootstrapping methods and high-level statistical programming.

Mahendra Shah, MD (Clinical coordinator), Department of Anesthesiology
Rush University Medical Center

Role: Dr. Shah will collect EHR records and transfer them to the study database. Also, assesses procedural variations and adverse events in the study.

Qualifications: Dr. Shah has been a clinical coordinator in this department for 4 years, involved in clinical studies on pain and its management.

Christine O'Neill, RN (Blinded Research Nurse), Department of Anesthesiology
Rush University Medical Center

Role: Ms. O'Neill will telephone subjects for the primary outcomes of the study: BPI, SF-36, PSQ-18

Qualifications: Ms. O'Neill has been a research nurse in this department for 2 years, involved in clinical studies on pain and its management.

Patricia Merriman, PhD (Psychologist), Department of Anesthesiology
Rush University Medical Center

Role: Perform psychological examination at the Rush Pain Center (including the Screener and Opioid Assessment for Patients with Pain–Revised (SOAPP–R)12), to determine risk of drug abuse.

Qualifications: Dr. Merriman has been the staff psychologist at the Rush Pain Center 4 years, and is involved in clinical studies on pain and its management.

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RUSH

Kenneth J. Tuman, MD
The Anthony D. Ivankovich, MD
Professor and Chairman

October 8, 2014

Asokumar Buvanendran, M.D.
Professor, Department of Anesthesiology
Rush University Medical Center
1653 W. Congress Parkway, Jelke 739
Chicago, Illinois 60515

Re: Letter of Support for the clinical trial entitled **"Improving functional outcomes and lowering Health care costs by enhanced integration of primary care providers and pain medicine physicians for the management of chronic non-cancer patients."**

Dear Dr. Buvanendran:

I have reviewed your study and am writing to confirm my enthusiasm and support for this grant application to investigate the collaboration between primary care providers and pain medicine physicians to manage patients with chronic pain. This randomized trial will answer a critical clinical question that will be of significant benefit to patients with chronic pain. The hypothesis that you propose is an exciting one with a firm medical foundation. The proposed protocol to best utilize clinical resources to reduce chronic pain would have an immediate and profound impact for the health care in the U.S.

As the Chairman of the Department of Anesthesiology at Rush University Medical Center, I confirm that you have my Department's full support for the duration of the project, and will provide the necessary resources to complete this project. In the 20 plus years that I have known you, you have been a very productive member of our Department with respect to both the clinical, and research aspects of your career. You have excelled in translational research in the arena of acute and chronic pain with an emphasis on outcome based clinical studies. Your efforts have culminated in a number of high quality peer reviewed publications including a lead article in the JAMA. This grant application is largely the consequence of identification of a number of important hypotheses that need to be tested based on your prior published clinical research. I am confident that you will again, successfully complete the proposed study, and that it will represent an important contribution to the general base of medical knowledge and clinical practice.

Your clinical practice is also diverse. Since completion of your fellowship in pain medicine in 2000, you have been working and contributing to one of the busiest interventional pain programs in the country. The Rush University Pain Center in which you work is a national referral center for patients with chronic pain and your extensive clinical experience in chronic pain is a key factor that will positively impact the success of the proposed project, (both design and conduct).

You also have gained a national and international reputation for your accomplishments in the area of pain management. For the current proposal, you have assembled a highly qualified individual as co-investigator for the current research proposal.

There is no doubt in my mind that when the current proposed research is completed, it will ultimately help determine the effectiveness of utilizing primary care providers, in collaboration with pain medicine physicians, to manage the large chronic pain population. The hypothesis and aims for the project are very clear and have significant clinical relevance. I am also confident that there should not be any difficulty in recruiting study subjects given the large number of patients seen annually at Rush University Pain Center.

Accordingly, the department whole-heartedly supports your twenty percent weekly time commitment to the study during its proposed 2 ½ year duration and will provide the necessary technical and administrative support needed to complete this project. If awarded this grant, I am confident that the proposed research and subsequent publication of the work will be completed in a systematic and timely fashion and the result will lay the groundwork for further research in this area of Pain Medicine that affects such a broad segment of our population.

Sincerely,

Kenneth J. Tuman, MD,
The Anthony D. Ivankovich, MD, Professor and Chairman
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RUSH

Amir K. Jaffer, MD, MBA, SFHM
Rush University Medical Center
Professor of Medicine
Senior Vice Chair, Clinical Affairs
Assistant Chief Medical Officer
Division Chief, Hospital Medicine

October 7, 2014

Asokumar Buvanendran, M.D.
Professor, Department of Anesthesiology
Rush University Medical Center
1653 W. Congress Parkway, Jelke 739
Chicago, Illinois 60515

Re: Letter of Support for the clinical trial entitled "**Improving functional outcomes and lowering health care costs by enhanced integration of primary care providers and pain medicine physicians for the management of chronic non-cancer pain patients.**"

Dear Dr. Buvanendran:

This letter is in support of your proposal to investigate the collaboration between primary care providers and pain medicine physicians to manage patients with chronic pain. As an Internal medicine provider, I accept the role of co-investigator.

I am currently Professor and Senior Vice Chair for Medical Affairs of the Department of Internal Medicine at Rush University Medical Center, as well as Associate Chief Medical Officer, Rush University Medical Center. I confirm that you have my full support for the 2 ½ -year project, and will provide the necessary resources to complete this project.

The hypothesis that you propose is an exciting one with a firm medical foundation. The proposed study when completed can have a direct impact on how the health care system of the U.S. is being utilized to manage the large chronic pain population.

Best regards,

Amir K. Jaffer, MD, MBA

PLACE PATIENT INFORMATION

STICKER HERE

RUSH PAIN CENTER
Informed Consent and Agreement for Controlled Substance Prescriptions

The purpose of this consent is to establish an expected code of conduct and prevent misunderstanding about certain medicines you are taking, or may begin taking, for pain management. This is to help both you and your physicians to comply with the laws regarding controlled substances/pharmaceuticals. In addition, the following cautions should be understood:

- Overuse or over dosage of pain medication can result in lethal side effects, including decreased ability to breathe and death. Use of alcohol increases these risks.
- Opioids may impair one's ability to drive and operate heavy machinery.
- If pregnant, narcotics should be continued only with approval of the patient's obstetrician/gynecologists.
- I understand that my continuation in treatment at the Pain Center is contingent on my compliance with the following terms and conditions and that I may be discharged from the Pain Clinic if I violate any of the following:

I acknowledge:

The goal of my treatment is to decrease my pain and improve my quality of life.

My medication(s) may be tapered and discontinued entirely if it is felt by my providers that I am not improving or fail to become more functional.

I will bring all medication containers for prescriptions written by my pain management physician to each visit.

If I lose my medication(s) or if they are stolen, I may have to do without medication(s) until my next regularly scheduled appointment.

I will communicate fully with my doctor about the character and intensity of my pain, the effect of the pain on my daily life, and how well medication is helping to decrease the pain and increase my functionality and activities of daily living.

I will not use any illegal substances, including marijuana, cocaine, methamphetamine, ecstasy, etc.

I will not use any controlled medicine(s), including opioids (narcotics), sedatives, stimulants, or anti-anxiety medications obtained from any other physician or source. The only exception being anti-anxiety medications prescribed by licensed mental health care practitioner.

I will safeguard my pain medicine from loss, theft, or use by others. Replacement of lost or stolen medicines will be considered only if I provide the doctor with a police report filed the day of the theft.

If a change in medication is made, I will return any medications remaining from the prior prescription to the pharmacy from which they were obtained in order to receive the new prescription.

I agree that refill requests of my prescriptions for pain medicine will be made only at the time of an office visit or during regular office hours. No refills will be available during evenings, weekends, or holidays. No prescriptions will be mailed.

I understand that if I break or do not comply with this Contract, my doctor will stop prescribing these controlled substances/pharmaceuticals. In this case, my doctor may or may not taper off the medicine, to minimize withdrawal symptoms. In addition, treatment through a drug-dependence treatment program/specialist and/or the Pain Center psychologist may be recommended.

I authorize the Rush Pain Center doctor and my pharmacy to cooperate fully with any city, state, or federal law enforcement agency, including this state's Board of Pharmacy, in the investigation of any possible misuse, sale, or other diversion of my pain medicine. I authorize the Rush Pain Center to provide a copy of this Contract to my pharmacy upon my request. I agree to waive any applicable privilege or right of privacy or confidentiality with respect to these authorizations.

I agree to voluntarily submit to a blood or urine test when request by my Rush Pain Center physician to determine my compliance with my program of pain control medication and to determine medication levels. A copy of this agreement will be provided to me. This testing will be done as described on the back of this page (A-J).

_____ _____

Patient's signature/Date Pain Center Staff Signature/Date

_____ _____

Patient's Printed Name/Date Witness/Date

PLACE PATIENT INFORMATION

STICKER HERE

Rush Pain Center/University Pain Centers

URINE DRUG TESTING PROTOCOL:

a) _____ Test every patient every 6 months if prescribed opioids and medicines
_____ Test on first office visit, if receiving prescription for opioids or benzodiazepines

Test patient at any office visit if they exhibit any of the following behaviors and note date of behavior:

b) Ran out of medication(s) early (>3 days):
Dates: _____ _____ _____ _____ _____

c) Lost prescription(s):
Dates: _____ _____ _____ _____ _____

d) Medication(s) stolen:
Dates: _____ _____ _____ _____ _____

e) Prescription(s) altered by patient:
Dates: _____ _____ _____ _____ _____

f) A family member reports the patient is abusing controlled substance(s):
Dates: _____ _____ _____ _____ _____

g) Use of illicit substance(s):
Dates: _____ _____ _____ _____ _____

h) Controlled substance(s) obtained from multiple providers, emergency room, or friends/family members:
Dates: _____ _____ _____ _____ _____

i) Significant change in patient's appearance/cognitive status:
Dates: _____ _____ _____ _____ _____

Patient Name: _____
MRN#: _____
DOB (mm/dd/yyyy): _____

PRIMARY CARE PROVIDER
(Physician, Nurse Practitioner, Physician Assistant)
Informed Consent and Agreement for Controlled Substance Prescriptions

The purpose of this consent is to establish an expected code of conduct and prevent misunderstanding about certain medicines you are taking, or may begin taking, for pain management. This is to help both you and your physicians to comply with the laws regarding controlled substances/pharmaceuticals. In addition, the following cautions should be understood:

- Overuse or over dosage of pain medication can result in lethal side effects, including decreased ability to breathe and death. Use of alcohol increases these risks.
- Opioids may impair one's ability to drive and operate heavy machinery.
- If pregnant, narcotics should be continued only with approval of the patient's obstetrician/gynecologists.
- I understand that my continuation in treatment with my primary care provider is contingent on my compliance with the following terms and conditions and that this type of treatment may be discontinued if I violate any of the following:

I acknowledge:

The goal of my treatment is to decrease my pain and improve my quality of life.

My medication(s) may be tapered and discontinued entirely if it is felt by my provider that I am not improving or fail to become more functional.

I will bring all medication containers for prescriptions written by my primary care provider to each visit.

If I lose my medication(s) or if they are stolen, I may have to do without medication(s) until my next regularly scheduled appointment.

I will communicate fully with my doctor about the character and intensity of my pain, the effect of the pain on my daily life, and how well medication is helping to decrease the pain and increase my functionality and activities of daily living.

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I understand that if I break or do not comply with this Contract, my provider will stop prescribing these controlled substances/pharmaceuticals. In this case, my doctor may or may not taper off the medicine, to minimize withdrawal symptoms. In addition, treatment through a drug-dependence treatment program/specialist and/or the Pain Center psychologist may be recommended.

I authorize my primary care provider and my pharmacy to cooperate fully with any city, state, or federal law enforcement agency, including this state's Board of Pharmacy, in the investigation of any possible misuse, sale, or other diversion of my pain medicine. I authorize my primary care provider to provide a copy of this Contract to my pharmacy upon my request. I agree to waive any applicable privilege or right of privacy or confidentiality with respect to these authorizations.

I agree to voluntarily submit to a blood or urine test when request by my primary care provider to determine my compliance with my program of pain control medication and to determine medication levels. A copy of this agreement will be provided to me. This testing will be done as described on the back of this page (A-J).

_____ _____
Patient's signature/Date Pain Center Staff Signature/Date

_____ _____
Patient's Printed Name/Date Witness/Date

Patient Name: _____
MRN#: _____
DOB (mm/dd/yyyy): _____

URINE DRUG TESTING PROTOCOL:

a) _____ Test every patient every 6 months if prescribed opioids and medicines
_____ Test on first office visit, if receiving prescription for opioids or benzodiazepines

Test patient at any office visit if they exhibit any of the following behaviors and note date of behavior:

b) Ran out of medication(s) early (>3 days):
Dates: _____ _____ _____ _____ _____

c) Lost prescription(s):
Dates: _____ _____ _____ _____ _____

d) Medication(s) stolen:
Dates: _____ _____ _____ _____ _____

e) Prescription(s) altered by patient:
Dates: _____ _____ _____ _____ _____

f) A family member reports the patient is abusing controlled substance(s):
Dates: _____ _____ _____ _____ _____

g) Use of illicit substance(s):
Dates: _____ _____ _____ _____ _____

h) Controlled substance(s) obtained from multiple providers, emergency room, or friends/family members:
Dates: _____ _____ _____ _____ _____

i) Significant change in patient's appearance/cognitive status:
Dates: _____ _____ _____ _____ _____