BRAIN MECHANISMS FOR CLINICAL PLACEBO IN CHRONIC PAIN:
A Randomized Clinical Trial of Placebo, Active Treatment, and No Treatment in Chronic Back Pain

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Study Drug/Study Device: Placebo, Naproxen, and Omeprazole

Funding Source: National Center for Complimentary and Integrative Health (NCCIH), National Institutes of Health

Initial version: **6/1/2016 (Phase 2)**
Amended:

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STUDY SCHEMA AND DESIGN

Design Schema for Objective 2 (Phase 2):

We intend to randomize 210 CBP patients into the study with the expectation that 140 will finish successfully. The entire duration of the study will be 12 weeks with an initial 3-week baseline period (visits 1-3), a 6-week treatment period (visits 3-5), and a final 3-week washout period (visits 5-6). During the baseline period eligible **participants will be predicted as placebo responders and non-responders** based upon baseline brain scan results and specific questionnaire answers (properties determined from the results of **Phase 1**) and then classified on that basis. Participants will then be randomized within each classification group (placebo responders and placebo non-responders) at a ratio of 3:3:1 such that 42.5% receive active medication (naproxen/omeprazole, 500/20mg, bid), 42.5% receive matching placebo treatment and 15% no treatment. Brain imaging, self-report questionnaire, and pain/mood rating measurement regimens are shown in **Figure 1**. Pain, mood, and pill ingestion will all be monitored by smart phone for the duration of the study, as well as determined in person at each visit.

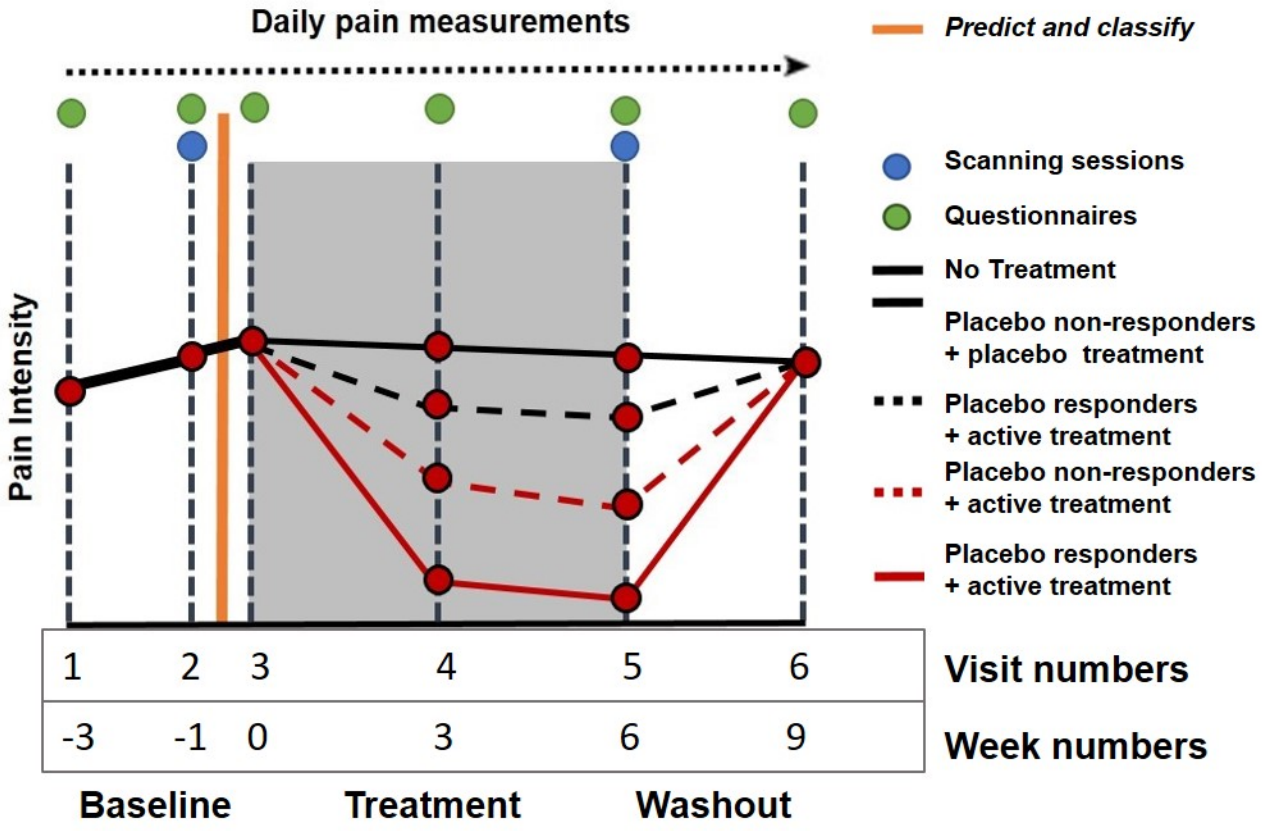

Figure 1. *Experimental schema for Phase 2. Expected changes in pain are shown in solid and dashed horizontal lines. We expect to see different pain outcomes for the various placebo and treatment combination groups.* To be noted, we predict that the No Treatment group will have similar pain trajectory as those classified Non-responders and treated with placebo. As well, in the No Treatment group participants will be classified as placebo responders and placebo non-responders, but will not receive any treatment agent, therefore, their pain trajectory will be constant throughout the study.

STUDY SUMMARY

Title	BRAIN MECHANISMS FOR CLINICAL PLACEBO IN CHRONIC PAIN
Short Title	PLACEBO IN CHRONIC PAIN (PICP)
Protocol Number	Grant:
Phase	Grant Phase 2
Methodology	Double blind, randomized (see section 5.4 for more specifics on blinding)
Study Duration	12 weeks
Study Center(s)	Northwestern University
Objectives	The overall purpose of Phase 1 was to identify brain mechanisms and behavioral markers of placebo analgesia propensity in chronic back pain patients. The markers identified in that phase will now be used in Phase 2 to predict placebo propensity in a separate cohort of chronic back pain patients and in turn, validate the markers' reliability to detect response. An additional objective of Phase 2 is to study the interaction of placebo propensity with active treatment.
Number of Subjects	A total of 340 participants will be enrolled across both phases. Phase 1 will have an expected enrollment of 130 participants to attain 64 completed participants Phase 2 will have an expected enrollment of 210 participants to attain 140 completed participants.
Diagnosis and Main Inclusion Criteria	Chronic back pain (history of low back pain for a minimum of 6 months with or without signs and symptoms of radiculopathy)
Study Product(s), Dose, Route, Regimen	Naproxen, 500mg, po and Omeprazole, 20 mg, po, and matching placebo capsules, all po bid
Duration of administration	6 weeks total for Phase 2 for all study products and treatments
Active Treatment	1 capsule Naproxen (500mg) /1 capsule Omeprazole (20 mg), both oral b.i.d.
Statistical Methodology	Brain activity contrasts are done as a two-way (treatment groups) repeated measures (time: start vs. end) ANOVA (two-way repeated measures-ANOVA). For responders, based on our preliminary results, we anticipate a mean decrease of 2.5 units on a 0-10 scales with an estimated SD of 3. Thus, the estimated Cohen's d effect size across time is an effect size estimate of 0.83.

1.0 BACKGROUND AND RATIONALE

1.1 Disease Background

The prevalence of chronic back pain (CBP) ranges from 15% to 45%, with the point prevalence averaging 30% (Andersson and Frymoyer, 1997). In the USA, chronic and acute back pains are the most common causes of activity limitation in people under 45, and the second most frequent reason for physician visits (Praemer et al., 1992; Hart et al., 1995). Whereas the few short-term (i.e. only weeks in length) placebo-controlled trials conducted to date have found some support for the use of non-steroidal anti-inflammatory drugs (NSAIDs) and antidepressants in treating lower back pain, their modest improvements in pain are not sufficient to achieve clinically-meaningful effectiveness. With efficacy requiring a minimum 20% decrease in pain compared to placebo, a meta-analysis of NSAID studies found no evidence that these drugs were more effective than placebo in treating CBP (van Tulder et al., 2000). Similar results have been observed for other classes of analgesics. The World Health Organization Advisory Panel has concluded that **there is no single treatment superior to others for relieving CBP (**Ehrlich, 2003).

Here we propose to study the brain circuitry, functionally and anatomically, for the placebo effect in treatment of patients with CBP. Our laboratory has extensively characterized the brain properties in CBP over the past 10 years. We have shown that brain activity in CBP is specific and distinct from that for acute pain (Baliki et al., 2006); brain resting state activity is disrupted in CBP (Baliki et al., 2008a; Baliki et al., 2011b); brain gray matter density is decreased in specific regions (Apkarian et al., 2004) and continues to reorganize on the time scale of 10 years (Baliki et al., 2011c). More recently, we have completed the first longitudinal brain imaging trial evaluating brain properties that predict pain persistence, and we have determined that brain functional properties measurable during the subacute phase (< 3 months back pain duration) can predict who will transition to CBP one year later (Baliki et al., 2012). These studies provide a solid scientific background upon which we can study brain characteristics of the placebo response in CBP.

1.2 Rationale

The *placebo effect* – an improvement in symptoms caused by receiving a sham treatment disguised to be indistinguishable from an active medical treatment - is a psychobiological phenomenon, coupled with underlying identifiable neurobiology. It has been observed across diseases, biological systems, and for a variety of treatments (Benedetti, 2008). Placebo shows the largest and most consistent effects in the realm of pain, and its potential clinical utility for analgesia has been recognized since the first studies of the topic (Beecher, 1955; Harrington, 1997). Moreover, a recent national survey of internists and rheumatologists in the US found that
approximately 50% of physicians prescribe medications they consider to have no effect on patients' conditions and are purposely used as placebos (Tilburt et al., 2008; Fassler et al., 2010). Thus, use of placebo in the clinic, whether knowingly or unknowingly, is highly prevalent. **Given that there is no single empirically-supported treatment for CBP, the use of placebo is justified in treatment studies of CBP.**

The bulk of the science of placebo has studied experimental manipulations in healthy subjects, and has convincingly established the psychobiological basis of placebo (Benedetti et al., 2011; Wager and Fields, 2012). In healthy subjects, placebo responses appear to reflect altered transmission in pain pathways, including a) reduced activity in many brain regions involved in acute pain perception; b) activation with placebo treatment of areas important for modulation of pain-related regions and engagement of descending pain modulating circuits; and c) activation of endogenous opioid and dopamine systems (Atlas et al., 2009; Tracey, 2010; Wager and Fields, 2012). Personality differences can contribute to placebo response magnitude, including high suggestibility (De Pascalis et al., 2002; Morton et al., 2010), optimism (Morton et al., 2009), expectation (Vase et al., 2003; Zubieta et al., 2005; Morton et al., 2010), behavioral activation (Schweinhardt et al., 2009), and sensitivity to opiates (Amanzio and Benedetti, 1999). These results are consistent with individual differences in how healthy subjects may respond differentially to trivial changes in placebo-related manipulations or contexts; however, no consistent evidence has supported a particular personality or psychological variable in mediating the placebo response. Perhaps most importantly, given the extensive brain reorganization with chronic pain, placebo

properties for pain modulation in chronic pain are likely distinct from those of healthy subjects.

Analgesia in the placebo arm is unequivocally observed in clinical trials, especially for chronic pain drug studies (Finniss et al., 2010). Until recently, placebo effects in the clinical setting have mostly been addressed using metaanalysis of such clinical trials (Enck et al., 2011). Recent studies show quite large placebo effects in clinical treatments (Kaptchuk et al., 2006; Haake et al., 2007; Kaptchuk et al., 2008b)), and in one case repeated sham treatment showed greater analgesia than conventional therapy in CBP patients (Haake et al., 2007). Similarly, comparing placebo effects in experimental and clinical back pain shows larger placebo effects for clinical pain (Charron et al., 2006), and placebo effects are larger with more sustained pain and in the presence of hyperalgesia (Vase et al., 2009). Therefore, placebo treatment in CBP has demonstrated effectiveness, and given the lack of evidence favoring any specific treatment for CBP, the study of placebo is warranted in this population.

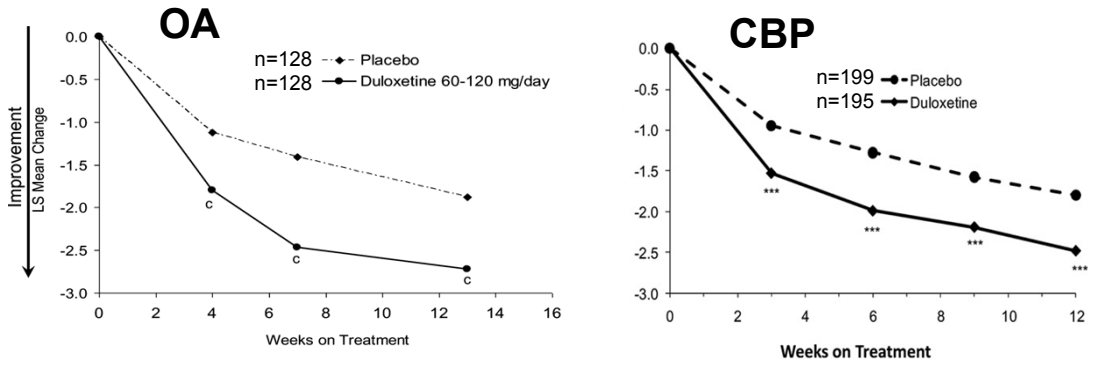

Figure 2: Effect magnitude for placebo and active treatment in OA and CBP for 12 weeks, (on a 0-10 scale). Data are from (Chappell, Desaiah et al. 2010, Skljarevski, Zhang et al. 2010, Skljarevski, Zhang et al. 2010).

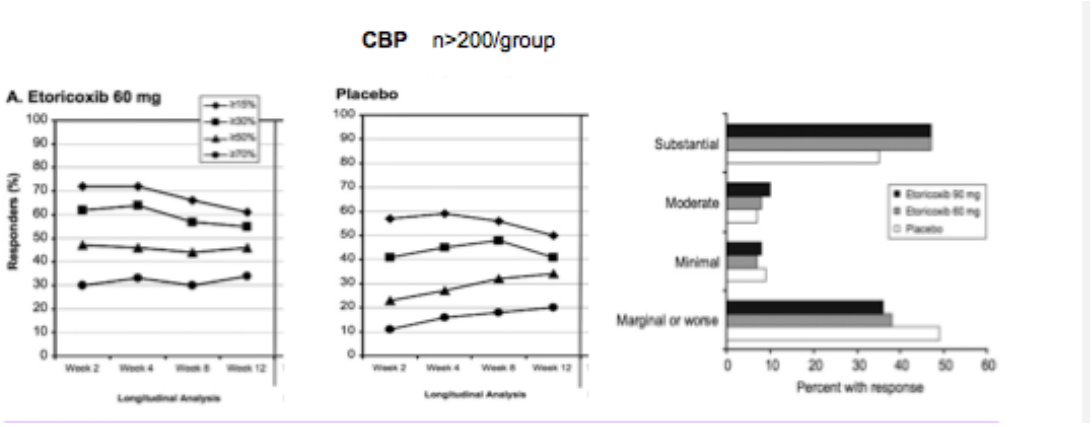

Figure 3: Percent CBP responders to active treatment and placebo, in time (left panels), and per category (right): marginal or worse <15%, minimal 15-30%, moderate 30-50%, substantial >50% decrease in pain. Data are from (Moore, Smugar et al. 2010).

The placebo effect is large and clinically significant in chronic pain. **Figures 2 and 3** depict recent (best quality) examples of phase 3 multi-center double-blind placebo-controlled drug trials in CBP and osteoarthritis (OA). These studies resulted in FDA approval for these drugs as effective therapies. Here we are interested in the reported placebo responses. It is evident how robust and similar the placebo

responses are across these studies, and how they are sustained for the entire study duration. In all three studies placebo decreases pain by at least 10% within 2-4 weeks and then by an additional 10-30% within 3 months. In **figure 3** (Cox2 NSAID study), placebo treatment decreased CBP pain by >50% in approximately 35% of the group. To unequivocally state that these are placebo responses, it is necessary to have a no-treatment, observation only, control group. Nonetheless, **figure 3** strongly suggests that the placebo effect may be dichotomous, hinting at the notion of two groups: responders and non-responders—this very notion is consistent with our preliminary results. Thus, *if we can identify chronic pain patients who will respond to placebo, then we can potentially decrease the pain in this group by about 30-50%, which would be highly clinically significant.*

Figures 2 and 3 also illustrate an important property of clinical placebo, namely a sustained relief from pain for many weeks. In contrast, experimental placebo studies, by design, only examine very short duration (hours to a few days) effects. Thus, brain circuitry identified for experimental placebo is unlikely to generalize to the clinically observed placebo effects. To our knowledge, using brain circuitry to predict the placebo response in the clinical setting has not been studied outside of our lab.

The current study design specifically addresses aspects of placebo trial design that have received ethical and scientific criticism. A recent review identifies 9 distinct potential sources of bias in placebo effect studies (Hrobjartsson et al., 2011). To circumvent these problems, we rely on randomized controlled trials (RCTs) and within-subject control washout periods, perform all procedures identically across all groups, all preliminary analyses are done blinded, un-blinding occurs only after the completion of data collection, and all primary outcomes are objective brain parameters. By controlling for these factors, the natural, biologically-based propensity for some subjects to be better placebo responders than others can be objectively identified based on the proposed clinical trials.

The proposed study of placebo analgesia in CBP is justified because there is currently no single empirically supported treatment for CBP pain. Given our ignorance of basic properties of placebo analgesia, such as reproducibility within individuals, duration of the response, and interactions with active medications, short-term studies are appropriate to address these issues. Furthermore, the active medication control group taking naproxen will receive a standard-of-care treatment , and all participants will be allowed to take acetaminophen (rescue medication) as needed. Although placebo is associated with side effects, there is evidence that symptom base rates associated with placebo are lower than those observed in the general population (Barsky et al., 2002). For these reasons, the scientific benefits outweigh potential risks that are attributable to placebo use.

In phase 1 of this grant, we expect to confirm our hypothesis that about 50% of CBP patients respond to a 2 weeks placebo treatment using smartphone to collect daily measurements of chronic pain intensity. On average and so far, participants showed very good compliance rate on the use of smartphone, reaching on average of 75%. Using these continuous measurements of chronic pain intensity, we expect to demonstrate that patients responding to a placebo treatment will show a robust reduction of about 25% of their pain intensity compared to their visit 1 to visit 2 ratings. This would confirm our preliminary observations that about half of enrolled CBP will respond to placebo treatment and that expected pain analgesia will be clinically meaningful.

1.3 Predictive neural and behavioral biomarkers for clinical placebo

Summary of main findings from Phase 1 Report:

1. Using the smart phone pain ratings and within subject permutation method provides a robust method for classifying placebo responders and non-responders.
2. Three emotion-related personality outcome measures (MAIA-not worry, MAIA-emotion, ERQ-suppress) together predict future placebo response at 94% accuracy. These measures are also correlated to questionnaires regarding alternative and complementary medicine including MISS (suggestibility),HCAMQ (holistic subscale) , and MLHC (health locus of control).
3. Resting state fMRI brain network information sharing between the frontal cortex and somatosensory cortex predicts placebo response at a very high accuracy.
4. Somatosensory cortex grey matter density predicts placebo response.

5. Brain white matter myelination properties do not predict placebo response.
6. Brain grey matter neurite orientation properties do not predict placebo response.
7. Limbic brain right to left asymmetry predicts placebo response.
8. The combined brain and personality final model predicts placebo response at 94% accuracy.

Conclusions from Phase 1 report:

1. The primary conclusion of these results is our ability to demonstrate that clinical placebo response is predictable from personality and from brain properties.
2. Identified personality parameters are distinct from those hypothesized in healthy subjects for experimental manipulations, and are consistent with CBP involving emotional circuitry. The relationship between these and attitudes to alternative medicine suggest common underlying mechanisms.
3. Functional information sharing results are based on a specific hypothesis we derive from our earlier similar study conducted in osteoarthritis patients, suggesting shared mechanisms of clinical placebo response predictive circuits.
4. The cortical gray matter prediction of placebo seems linked to the functional information sharing circuit and probably reflects inter-related measures.
5. The fact that we did not find a whole-brain contrast in white matter myelination properties to predict placebo response was expected and not surprising. It is possible that the white matter connectivity between the functional networks may still be distinct (remains to be tested).
6. Perhaps the most surprising and intriguing result is the observation that limbic brain hemispheric volume asymmetry predicts placebo response. Our earlier work (paper submitted) shows that these brain volumes are invariant over up to 3 years even when subjects develop chronic pain, which implies that these structures are mostly fixed in adulthood and thus suggest that clinical placebo propensity is, at least in part, a trait.

1.4 Correlative Studies

Brain imaging as a tool for making clinical decisions in chronic pain populations is not a practical option, as it requires highly sophisticated technology and analysis tools. No existing scale (or combination of scales) can predict the likelihood that a given individual with chronic pain will respond positively to a placebo treatment. There has been a strong bias against the development of such tools based on observations that placebo response in healthy subjects is highly variable, despite some progress in the topic (Shapiro et al., 1975; Wilcox et al., 1992; Geers et al., 2005; Geers et al., 2010). In contrast, our preliminary results strongly suggest that a Tool for Placebo Propensity Prediction (or TOPPP) can be developed because, in chronic pain, the placebo response is an objective, predictable phenomenon. Given the considerable potential clinical benefits of a measure like TOPPP, there is a need for a measurement system that is sufficiently sensitive to identify propensity for placebo analgesia that is brief, yet precise, easy to implement, and correlates with objective parameters of placebo response, such as brain imaging parameters.

2.0 STUDY OBJECTIVES

2.1 Primary and Secondary Objectives

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2.1.1 To evaluate the interaction between placebo response and active treatment in individuals classified as placebo responders vs non-responders. Individuals in the No Treatment group will be used as a negative control to control for regression to the mean, duration of pain, and other potential confounds.

Hypothesis: Brain functional and anatomical properties between groups after 6 weeks of treatment will identify separate circuitry for placebo analgesia and active treatment analgesia; and these groups will show distinct time courses and magnitudes of analgesia.

2.1.2 To test and validate brain imaging and personality parameters identified in Phase 1 that predict the propensity for placebo response and use the results to classify participants into responders vs non-responders before study intervention.

Hypothesis: Brain- and behavioral- based parameters identified as markers of placebo response in the first phase of the study will accurately predict potential responders from non-responders at first scan. The classification before study intervention will closely correspond to the responses observed at the end of treatment period.

2.1.3 To identify gender dependence of placebo analgesia propensity and examine brain and personality gender differences that underlie the seeming higher propensity of females for placebo response.

Hypothesis: Sexual dimorphism of the human brain and behavioral/personality differences may have a potential interaction effect and predisposition on placebo propensity. We expect to identify gender-specific biomarkers that are sexually dimorphic with regard to placebo response.

2.1.4 Classification of placebo responders versus non-responders for 2.1.2 will be based on Equation 1 below:

$p = (e^{f(x)})/(e^{f(x)} + 1)$

$f(x) = -3.3586 + 1.6676*Maia\_Emotion - 0.2127*Erq\_Suppress + 34.8608*sign\_permutation$

where a probability (p) <0.5 = predicts non-responder and a probability (p) ≥0.50 predicts responder.

These objectives evaluate the notion that placebo effects can be reduced, and perhaps eliminated, from drug trials, by showing that identifiable, separate circuits underlie modulation of pain by each. Additionally, we test the utility of combining a drug treatment with placebo effects. The RCT literature for testing drug efficacy has repeatedly stumbled, in that one study may be successful yet the next fails. One can envision that chance differences in the number of placebo responders and non-responders entering the study may dictate the success of many RCTs. This aim intends to clarify whether placebo responders show medication treatment responses superior to the placebo response, or whether the two independently summate for resultant analgesia. This provides the first effort for dissociating brain activity when pain is modulated by placebo versus medication. As the medication we will study is an NSAID, we assume that its main site of action is the peripheral nervous system and the spinal cord, whereas the placebo effect is obviously mediated through cortical control. Thus, we also dissociate between bottom up and top down modulation of chronic pain. Furthermore, we will begin to identify gender-dependence interactions

on placebo propensity and elucidate sexual dimorphisms in functional and anatomical brain properties in the domain of placebo response.

2.2 Exploratory Objectives

Self-report data from Phase 1, in the form of questionnaire answers and interview answers, will be used to develop and validate a self-measurement Tool for Placebo Propensity (TOPPP) to be tested here in Phase 2. Additionally, biomarkers for placebo response identified in Phase 1 will be validated in this phase via the initial stratification into predicted responders versus non-responders at the beginning of the study.

Specifically, the brain circuits we observe for placebo propensity reflect interactions between the lateral prefrontal cortex and pain processing areas, (this is now confirmed from Phase 1 results), and these pain and disease properties should be readily identified in personality, expectation, and medical exposure appraisals (measurements we collected from specific questionnaires; emotional responses seem to best capture placebo propensity in Phase 1 results), as well as captured from themes and patterns seen in qualitative interview responses (this data remains to be analyzed from Phase 1 data) from the previous phase. Significant differences in questionnaire scores (total scores and/or specific subscores) between placebo responders and non-responders, as well as qualitative and quantitative differences seen between these groups in their responses to interview questions, will inform us as to which variables we should use in our new tool tool (we now have such a tool from Phase 1 results) that may have predictive capacity. This tool will be used in combination with brain biomarkers in the second phase to help stratify participants into responders versus non-responders at the first scan, using all new CBP participants as a validation group.

This multi-method approach maximizes the likelihood that we will identify self-report variables uniquely linked to the placebo response and its neural signature by including items that capture the unique characteristics of chronic back pain and their treatment effects, spanning the disease continuum and producing scores calibrated onto a common metric. Importantly, a system that meets these needs is likely to be accepted and routinely used in clinical and research settings.

2.3 Endpoints

2.3.1 Endpoint for primary objective: (1) Placebo response (defined as > 20% reduction in pain intensity following placebo treatment, or defined from pain app ratings using permutation with 0.05 p-value cut-off)) versus active treatment response (reduction in pain intensity following naproxen/omeprazole treatment)

2.3.2 Endpoints for secondary objective: (1) Testing the specificity and sensitivity of the brain and behavioral parameters from Phase 1, in combination with the TOPPP developed from the study interviews, as predictive markers for response in Phase 2. These parameters will be considered validated if together are at least 80% accurate in stratifying responders from non-responders.

2.3.3 Endpoint for gender objective: (1) Testing for females showing higher incidence of placebo response using combined outcomes from phase 1 and phase 2 data.

3.0 PATIENT ELIGIBILITY: SELECTION AND ENROLLMENT OF PARTICIPANTS

Subjects must meet all of the inclusion and exclusion criteria to be registered to the study. Study treatment may not begin until a subject is registered.

3.1 Inclusion Criteria

3.1.1 History of low back pain for a minimum of 6 months with or without signs and symptoms of radiculopathy
3.1.2 Male or female, between the ages of 18 and 75 years, with no racial/ethnic restrictions
3.1.3 Must have a Visual Analog Scale (VAS) pain score $\geq$ 5 mm (of 10 mm maximum) at the screening visit (for which 0mm = no pain, and 10 mm = worst pain imaginable);
3.1.4 Must be able to read and speak English and be willing to read and understand instructions as well as questionnaires;
3.1.5 Must be in generally stable health;
3.1.6 Must sign an informed consent document after a complete explanation of the study documenting that they understand the purpose of the study, procedures to be undertaken, possible benefits, potential risks, and are willing to participate
3.1.7 Must have, on average, $\geq$ to 5/10 units of pain over the course of a two-week period prior to visit 1; rounding up from 4.5/10 is permissible.
3.1.8 Must be willing to complete daily smart phone/computer app ratings.

3.2 Exclusion Criteria

3.2.1 Low back pain associated with any systemic signs or symptoms, e.g., fever, chills;
3.2.2 Evidence of rheumatoid arthritis, ankylosing spondylitis, acute vertebral fractures, fibromyalgia, history of tumor in the back;
3.2.3 Other comorbid chronic pain or neurological conditions;
3.2.4 Involvement in litigation regarding their back pain or having a disability claim or receiving workman's compensation or seeking either as a result of their low back pain;
3.2.5 Diagnosis of current depression or psychiatric disorder requiring treatment, or such a diagnosis in the previous 6 months;
3.2.6 Beck Depression Inventory (BDI) Ia score >=19 for two consecutive completions; if the first score meets this criteria, the participant must be re-tested before his/her next visit, but if the second score does not meet this criteria, the participant will be included and followed closely throughout the study
3.2.7 Use of therapeutic doses of antidepressant medications (i.e., tricyclic depressants, SSRIs, SNRIs; low doses used for sleep may be allowed);
3.2.8 Significant other medical disease such as unstable diabetes mellitus, congestive heart failure, coronary or peripheral vascular disease, chronic obstructive lung disease, or malignancy;
3.2.9 History of gastrointestinal ulcer during the past year;
3.2.10 History of myocardial infarction in the past year;
3.2.11 Uncontrolled hypertension;
3.2.12 Renal insufficiency;
3.2.13 Allergic to, or non-tolerant of, NSAIDs;
3.2.14 History of aspirin-sensitive asthma;
3.2.15 Current use of recreational drugs or history of alcohol or drug abuse;
3.2.16 Any change in medication for back pain in the last 30 days only applicable for visit 1
3.2.17 High dose opioid prophylaxis, as defined as > 50mg morphine equivalent/day;
3.2.18 Any medical condition that in the investigator's judgment may prevent the individual from completing the study or put the individual at undue risk;
3.2.19 In the judgment of the investigator, unable or unwilling to follow protocol and instructions;
3.2.20 Evidence of poor treatment compliance, in the judgment of the investigator;
3.2.21 Intra-axial implants (e.g. spinal cord stimulators or pumps);
3.2.22 All exclusion criteria for MR safety: any metallic implants, brain or skull abnormalities, tattoos on large body parts, and claustrophobia;
3.2.23 Pregnancy, or inability to use an effective form of contraception in women of child-bearing age;
3.2.24 Diabetes (Type I or Type II);
3.2.25 < 5/10 pain on average over the two-week period before the visit 2;
3.2.26 Lactose intolerance or sensitivity to lactose; and

3.3 Recruitment

Potential subjects will be recruited initially from a database maintained by the PI and from Northwestern's EDW. Once these sources are depleted, it is envisioned that recruitment will occur via community, online, and flyer-based methods, including ads. Potential subjects from our internal database who have provided agreement to be contacted will be called by the research staff. Those identified via EDW will be contacted once permission is granted by their physician, either by phone or by an IRB-approved mailing to be generated. Potential subjects may also be recruited online through websites including but not limited to ClinicalTrials.gov; sites for professionals who see patients with low back pain or related conditions; social media websites such as Facebook and Twitter; and/or people with low back pain or related conditions. This study will also use another online recruitment tool called Research Match, which is a secure online, national recruitment tool that is maintained by Vanderbilt University. ResearchMatch.org allows researchers to conduct feasibility or recruit potential study participants.

If potential subjects are interested in the study, they will be able to contact the research staff via the telephone number given on the website or click on a link to complete a brief online screener. To facilitate the recruitment of similar studies on low back pain conducted by Dr. Apkarian's lab at Northwestern, participants who are screened will be asked if they are interested in learning about and participating in other studies on low back pain. If participants agree, they will be referred to and pre-screened for the other low back pain studies.

3.4 Screening

Before a person can be enrolled in the study and participate in Visit 1 (Screening Visit), s/he must first go through a maximum of two screening procedures over the phone. For potential participants who are recruited through community, online (including ClinicalTrials.gov), and flier/ad-based methods, the telephone number they contact will direct them to either NUCATS or research personnel associated with this study. NUCATS will go over a very brief pre-screening phone interview with interested individuals to verify that they are eligible to participate in the study at the most basic level (for example, verifying that they don't have any comorbid pain conditions and average pain prior to study enrollment). Those individuals who pass this pre-screening phone interview will have their contact information given to the study coordinators for a more thorough phone screening process. For these potential subjects and for individuals being recruited from the databases mentioned in 3.3, research coordinators will contact them and ask a series of more detailed questions to verify eligibility to enroll. This phone screening will go over all inclusion and exclusion criteria as indicated in the protocol, and it will also briefly explain the purpose of the study and the general outline the study. If the individual is eligible and still interested in participating at the end of this longer phone screening, the coordinator will schedule a time for them to come in for Visit 1. Additional screening procedures will happen at the first and second visits (for example, a pain rating >5/10 and discontinuation of contradictory medicines), and final eligibility will not be determined until the day before the first scan at visit 3.

4.0 TREATMENT PLAN AND STUDY INTERVENTION

4.1 Treatment Dosage and Administration

4.1.1 **Placebo Treatment:** Placebo capsules (gel caps filled with lactose NF), which will look identical to the active treatment capsules (see below), will be taken twice daily during treatment periods. During Phase 2, after a initial rating period and a 2-3 week washout of any of participant's current pain medications, participants will take placebo orally bid for 6 consecutive weeks (coming in every 3 weeks for follow-up visits and medication refills), followed by an additional 3 week washout period before study completion. One placebo

pill will be capsulated similarly to naproxen and the other will be encapsulated similarly to omeprazole.

The manufacturer for the placebo is Humco. The capsule shells (hard gelatin) will be manufactured by Capsugel (Coni Snap Size 00). Capsugel provides a certificate of analysis with each capsule batch ordered. Capsugel manufactures gelatin capsules from gelatin that complies with BSE requirements. Capsugel provides confidential detailed information about facilities, processes, articles used in manufacturing, processing, packaging, and storing of empty capsules through Type IV (Excipient) Drug Master Files submitted to the FDA. Inactive ingredients are cellulose and gelatin. Placebo capsules also contain FDC Blue #1 and FDC White.

4.1.2 **Active treatment:** 1 capsule of naproxen (500mg) and 1 capsule of omeprazole (20mg) will be taken orally twice daily based on the protocol for Phase 2 outlined in [3.1.1]. Each of these pills is encapsulated differently to avoid potential confusion when taking the medication. The active ingredient for the Naproxen tablets manufactured by Teva Pharmaceuticals or Amneal Pharmaceuticals, and the active ingredient for omeprazole is manufactured by Kremers. The capsule shells for both naproxen and omeprazole are manufactured by Capsugel and are the same material, size and color as those for the placebo (see 3.1.1. above).

4.1.3 **No-treatment:** For individuals assigned to the no treatment group, they will have the opportunity at the end of the study (when the study is un-blinded and when the efficacy results have been analyzed) to try the study medication that worked the best in alleviating back pain in the other participants, regardless of whether it was the NSAID or the placebo. If requested, this medication will be given to them at the same dosage and frequency that was used in the study, and the amount provided will last 6 weeks.

4.1.4 **Acquisition:** The study medications – lactose NF, Naproxen, and Omeprazole – will be purchased by the Investigational Research Pharmacy at NMH, 251 E Huron St. LC-700, Chicago, IL 60611. Lactose NF will be purchased in bulk and the naproxen and omeprazole as capsules from the manufacturers noted above.

4.1.5 **Formulation, Packaging, and Labeling:** Over-encapsulation is conducted in the Investigational Pharmacy on a segregated and cleaned countertop. Active capsules are prepared by putting the active drug capsule inside an empty gel cap and further filling it with lactose. Placebo capsules are made by filling an empty gel cap with lactose.

4.1.6 **Product Storage and Stability**: Study agents will be stored at temperatures between 68-77 ºF. Shelf life for Placebo and Omeprazole is 6 months; shelf life for Naproxen is 6 months. Shelf life for the rescue medication (acetaminophen) will be determined by the expiration date provided on the purchased bottles. Study medications will be stored and monitored at the Research Pharmacy; rescue medication will be stored in a designated locked filing cabinet in a locked room and will be monitored daily via temperature and accountability logs.

4.1.7 **Accountability Procedures:** Study product will be purchased by Northwestern Memorial Hospital Investigational Pharmacy for over-encapsulation; the rescue medication – Acetaminophen – will be bought in bulk from a nearby Walgreens pharmacy by the research staff. A defined quantity of capsules of study agent (naproxen, omeprazole, and placebo) will be supplied by NMH Investigational Pharmacy for distribution to participants. Each bottle of study agent will be filled with 52 capsules of the study agent designated by the randomization scheme – this number was calculated based on having two consecutive 3-week (21 day) treatment periods plus the additional 5 day possible visit window (26 days) multiplied by two pills a day; participants would receive a set of 2 bottles (one with 52 blue pills and another with 52 bi-colored pills) at visit 3 and another set of 2 bottles and visit 4. Regarding rescue medication, 8 pills of acetaminophen

(500mg each) will be provided at visits 1 through visit 5 by the research staff. This low number is to diminish the likelihood that participants will have a placebo response to the rescue medication and encourage them to only use the medication IF they truly need it.

Participants will be required to record all medication usage using the phone/computer app. These data are immediately logged into our server, which provides us routine overview of participants' participation and compliance, and further enhances retention of participants. If participants repeatedly miss entering these values, they are contacted by phone and instructed for compliance. A member of the research staff, unblinded monitor (Taha Abdullah, Back up: Ian Lukidis), will contact those participants who are non-compliant with phone app ratings. Thus she will be the only staff member who will be unblinded to treatment allocation (treatment vs no treatment) Participants will be asked to return all unused study medication for each treatment visit and it will be accounted by the research pharmacy. An overall usage rate of 80% is required to be considered compliant; if a participant falls below this percentage, we will still keep them in the study but we may or may not end up using their data for future analyses. A final inventory at study conclusion will be compared with drug supplied, drug participant recorded taking, drug participants actually took, and drug returned. Returned medication will be destroyed through NMH pharmacy drug disposal services after final accountability is determined. The pharmacy will be responsible for updating and checking the study agent accountability logs. Rescue medication will only be dispensed for visits 1-5 and accountability will be determined by the research pharmacy and documented in a rescue agent accountability log. Returned medication will be destroyed through NMH pharmacy drug disposal service after final accountability is determined.

4.1.8 **Concomitant Medications/Treatments:** Participants must discontinue all concomitant pain medications prior to starting study treatment. Participants will be required to restrict all medications for relief of pain to only those provided during the course of this study (i.e., rescue medication, acetaminophen). Participants will be allowed to continue their existing non-pain medications as long as they are not exclusionary for study enrollment. Concomitant Medications/Treatments. Any changes in pain medication during the 30 days prior to visit 1 are not permitted, and a history of alcohol or drug abuse within the last 3 years is prohibited. Prior cannabinoid drug use is not exclusionary, but must be stopped for the duration of the study; if there is evidence that the participant is currently using cannabinoids or other recreational drugs while enrolled in the study, s/he will be dropped. Participants will be queried at each visit about other medications they are taken and any changes to this list. A cumulative log of medications will be kept in their designated study folder. Additionally, Northwestern University has an online database called eNOTIS, which is a web-based study enrollment log run by NUCATS that helps improve safety and security for participants. eNOTIS allows investigators to track participants involvement in other studies and in turn monitor if they are using other interventions from these studies at the same time. All participants are entered into eNOTIS at the beginning of the study so that we can record any of these possible interventions throughout the person's time in the study.

4.2 Duration of Therapy

Treatment may continue for **6 weeks** or until:

- Inter-current illness prevents further administration of treatment;
- Unacceptable adverse event(s);
- Patient decides to withdraw from the study; **OR**
- General or specific changes in the patient's condition render the patient unacceptable for further treatment in the judgment of the investigator.

4.3 Intervention Discontinuation: Removal of Patients from Protocol Therapy

Subjects have the right to withdraw fully or partially from the study at any time and for any reason without prejudice to his or her future medical care by the physician or at the institution. Withdrawal of full consent for a study means that the subject does not wish to receive further investigational treatment and does not wish to or is unable to continue further study participation; subject data up to withdrawal of consent will be included in the analysis of the study. Any subject may withdraw full consent to participate in the study at any time during the study. The investigator will discuss with the subject appropriate procedures for withdrawal from the study.

Withdrawal of partial consent for a study means that the subject does not wish to take protocol-required interventions any longer but is still willing to collaborate in providing further data by continuing on study (e.g., participate in all subsequent study visits or procedures). Subjects may decline to continue receiving interventions at any time during the study. If this occurs, the investigator will discuss with the subject appropriate procedures for withdrawal from protocol-required therapies (since this is placebo, there will be not withdrawal period; they can simply stop treatment). Should a subject (or a legally acceptable representative) request or decide to withdraw from the study, all efforts will be made to complete and report the observations as thoroughly as possible up to the date of withdrawal. All information should be reported on the applicable forms.

Reasons for intervention discontinuation might include:
- partial withdrawal of consent
- withdrawal of full consent
- administrative decision by the investigator
- pregnancy in a female subject (cannot be scanned)
- sudden ineligibility due to another intervention, accident, etc
- significant protocol deviation
- patient noncompliance, which may include but is not limited to:

    1. not taking the study medication (if applicable) according to the instructions given this will be monitored according to the phone/computer apps and in-person visits; if a participant has multiple indications of medication non-compliance, s/he will be disqualified and the intervention will be stopped
    2. taking non-approved concomitant medication (section 4.2)
        a. this will be monitored according to the phone/computer apps, in-person visits, and eNOTIS
    3. not completing required study tasks, such as the daily phone/computer application
        a. more specifically, if a participant misses 3 consecutive ratings, the research coordinator will be informed and s/he will call the person to remind them;

- AE
- other safety concerns by the investigator or NCCIH
- death
- lost to follow-up

If a patient's intervention is discontinued, the Principal Investigator will be informed, the reason for study removal will be documented, and the date the patient was removed will be listed in the Case Report Form.

4.4 Subject Retention and Ensuring an Adequate Sample Size

Although accrual will be monitored on a quarterly basis according to our DSMP, at designated time points throughout each aim of the study, we will assess whether or not we need to recruit additional participants. For Phase 2 this will be done at the half-way point and repeated for every 2 blocks until completion. At these times, if there is not a large enough drop-out rate to significantly reduce our sample size or power, we will not attempt to replace participants and continue with analysis without any replacement strategy. However, if the drop-out rate is larger than expected and lack of study retention causes us to need to increase our sample size, we will recruit additional participants and have NUCATS randomize accordingly until we have enough

participants in each group to do adequate analyses. In other words, we will continue to enroll subjects until we have an adequate number that meet our criteria, using the original randomization list. As addressed previously, we have specific procedures to help minimize subject dropout and missing data. These include the collection of detailed contact information from subjects, maintaining communications logs regarding our contacts with subjects, and a "study identity" that we will use in various communications with subjects (e.g., phone, email, letters). The computer/phone application mentioned previously will also aid us in retaining and tracking our subjects, as well as keeping up with data collection. As subjects drop out of the study, we will document reasons for dropout and address any procedural issues that may be related to dropout. At regular team meetings, we will review the number and percentage of missed assessments. Even with our data-retention plan, there will of course be missing data over time. We will compare subjects with and without missing data to determine whether any subject characteristics are systematically related to missing data. All relationships over time can be analyzed using hierarchical linear modeling (HLM), which provides maximum likelihood estimates for model parameters when data are missing at random. This model is a mixed-effects repeated measures (MMRM) analyses that includes data over time nested within participants. Participant-level variables are included in the model. For this model, participant level variables will be *Maia_Emotion*, *Erq_Suppress*, and *sign_permutation*, just as in the logistic regression model (described above). HLM allows one to model the trajectory of change within subjects, and then determine the effects of covariates (e.g., treatment group) on this trajectory. The exact model tested will be:

$$PAIN_{ti} = \beta_{00} + \beta_{01}*MAIA\_EMO_i + \beta_{02}*ERQ\_SUPP_i + \beta_{03}*SIGN\_PER_i + \beta_{10}*DAY_{ti} + \beta_{11}*MAIA\_EMO_i*DAY_{ti} + \beta_{12}*ERQ\_SUPP_i*DAY_{ti} + \beta_{13}*SIGN\_PER_i*DAY_{ti} + r_{0i} + r_{1i}*DAY_{ti} + e_{ti}$$

In the equation above, $PAIN_{ti}$ is the average pain rating for the *t*th day for the *i*th participant. *r* and *e* terms are error terms. Parameters will be solved for by maximum likelihood estimation. It should be noted that all aspects of this model will be inspected in Phase 2 and alternative models will be examined as needed. This includes models with more complex pain trajectories (e.g., non-linear change over time), and models with additional covariates and/or interactions among covariates

5.0 STUDY PROCEDURES

5.1 Screening and Enrollment Procedures

Assessments performed exclusively to determine eligibility for this study will be done only after obtaining informed consent. Assessments performed for clinical indications (not exclusively to determine study eligibility) may be used for baseline values even if the studies were done before informed consent was obtained.

All screening procedures must be performed within 28 days prior to randomization unless otherwise stated. The screening procedures include:

5.1.1 ***Informed Consent***

Read and discuss informed consent form (ICF) and receive signature from participant and study personnel asking for consent. An ICF template is attached to the appendix of this protocol.

5.1.2 ***Medical history***

Complete medical and surgical history, history of infections

5.1.3 ***Demographics***

Age, gender, race, ethnicity, socioeconomic status

5.1.4 *Review subject eligibility criteria*

See section 2.0 above

5.1.5 *Review previous and concomitant medications*

See section 3.2 above

5.1.6 *Physical exam including vital signs, height and weight*

Vital signs (temperature, pulse, respirations, blood pressure), height, weight

5.1.7 *Review of pain intensity stability*

Pain levels ≥ 5/10 intensity are required to be reported prior to study entry. This criteria must be maintained on average for 2 weeks during the baseline rating period in order to continue in the study at visit 2.

5.1.8 *Adverse event assessment*

N/A for Screening; AEs will be collected at Visit 2 and all further visits. See section 6.0 and DSMP (in appendix) for Adverse Event monitoring and reporting.

5.2 Procedures During Treatment

5.2.1 Schedule of Events for all participants

- Visit 1 (week-3): Consent, screening, and baseline pain/mood monitoring (45 min). Participants will complete the informed consent process and are evaluated for initial inclusion/exclusion criteria, and they will be asked to assess current back pain intensity on a VAS scale. They will be asked to assess current back pain intensity on a VAS scale (0-10mm, no pain to worst possible pain). A medical/pain history and physical examination including vitals will be completed. Blood will be drawn for an initial screen to obtain a complete blood count, chemistry panel, and liver function tests (data reviewed by TJS). Participants will be asked to discontinue their current pain medications ~14 days (2 weeks) prior to their first scanning visit. Participants will receive acetaminophen (rescue medication) at the time of the visit. They will be shown how to use the smart phone/computer application (and given a phone if necessary), and they will be instructed to rate their pain and mood with the app two times a day for the duration of the study. Participants will complete questionnaires and return within 2 weeks for the first MR imaging scans. This length of time is adequate to allow scheduling and permit flexibility for subjects' preferences, and to ensure that pain levels persist at or above 5/10 VAS collected from the pain rating app and that participants do not significantly respond (>20% decrease) to the acetaminophen rescue medication. In addition, the entry interview will be conducted at this visit.

- Visit 2 (week -1): Baseline Scan (90 min).
  Approximately 14 days after visit 1, participants will return for their second visit. If a VAS score of > 5 mm on average over the course of the visit 1-visit 2 rating period is calculated and no changes in clinical status are reported or found, they complete a battery of questionnaires and undergo MRI procedures (anatomical and functional scans). Subjects will be queried about changes to health experienced since the last visit and asked if they exceeded 4 acetaminophen per day. In addition one of the pictures for visit 2, 4, and 5 will be conducted (see section 13.III). They will be asked to continue their phone/computer app ratings and return in approximately one week for visit 3. Participants will receive only rescue medication in sufficient quantities until the next visit. Additionally, participants will be randomized into a treatment versus no-treatment group at this time (information that the pharmacy will produce and keep).

- Interim between Visit 2 and Visit 3: Group classification Based on Predicted Response

In between visits 2 and 3, participant's scans will be analyzed by extracting the functional connectivity between frontal and sensorimotor networks (called "sign permutation" in Equation 1) and 2 questionnaire subscores will be calculated (MAIA emotion and ERQ suppression in Equation 1); all 3 parameters will then be entered into Equation 1. Based on the results of the model specified on page 10, participants will be classified as either placebo non-responders (probability < 0.5) or placebo responders (probability ≥ 0.5).

After baseline scan, the subjects' MR images and data will be collected by research personnel and then will be given to a single member, the blinded assessor (Dr. Huang) who will have no interaction with the participants, therefore will remain blinded. The research personnel responsible for conducting the visit will download the MAIA and ERQ questionnaires from the REDCap database and calculate the scores for MAIA-Emotion and ERQ-suppression subscales to be used in the model.

(1) All MR images collected at the baseline scan will be uploaded to the server and pre-processed within 24 hours of the visit using our in-house pipeline.

(2) The blinded assessor will be responsible for initiating the preprocessing of the brain images and extracting the connectivity values between frontal and sensorimotor regions ("sign permutation value"). This extraction will be done within 4 days after the MRI was collected, which provides enough time to calculate this connectivity and the likelihood of response (see below), as well as adequate time to give the result to the pharmacy (see below).

(3) After obtaining the connectivity values, the blinded assessor will enter these along with the 2 questionnaire subscores into the model on page 10 to determine subject group identification. The model generates a response likelihood from 0 to 1, and those individuals with a p-value ≥ 0.5 will be labeled as responders; all others will be labeled as non-responders.

(4) After response group identification, the blinded assessor will then send an email with subject ID, classification group, and randomization code to the Northwestern University Research Pharmacy email NMInvestigationalDrugService@nm.org. The research pharmacy will have two independent randomization sequences for responders (Group A) and non-responders (Group B). Each group independently will be allocated in a 3:3:1 ratio (active treatment, placebo treatment, and no treatment, respectively) by the research pharmacy. Therefore, the pharmacist will be unblinded to identification and treatment allocation.

The unblinded monitor who is responsible for phone app compliance will be partially unblinded, remaining blinded to active vs placebo assignments but unblinded with respect to treatment vs no treatment groups, as the pain rating app will query participants "Have you taken today's medication?" The remaining staff members will be completely blinded to both treatment vs no-treatment allocation and within the treatment allocation to active vs placebo treatments

A one-week interim period was chosen to allow enough time for selected study staff to run the prediction analysis and send this information to the pharmacy, as well provide another week of additional baseline pain app ratings. The duration of this period might be slightly longer or shorter depending upon how quickly the model is run, but it will be within the visit window specified in this protocol, which is ± 5 days

- Visit 3 (week 0): Start of Treatment Period (30-45 min).
  Once classification has been made with regard to responder vs non-responder status participants will return for the next visit (V3). A set of questionnaires will be administered

and participants will be queried about changes to health experienced since the last visit. Vitals will also be collected. Participants who remain eligible will then be randomized to active treatment, placebo, or no treatment groups in a blinded fashion, which will be completed by the research pharmacy. The unblinded monitor will pick up study drug from the pharmacy prior to visit 3, if the participant is assigned to the treatment arm. Additionally, participants will receive only rescue medication in sufficient quantities until the next visit. The unblinded monitor will explain the medication regimen to the participant at that time. This is to ensure that the remaining study staff remain blind to treatment versus no-treatment group assignment. The placebo group, made up of predicted responders and non-responders, will receive two placebo capsules bid, and the active treatment group, also made up of predicted responders and non-responders, will receive one naproxen capsule (500mg) and one omeprazole capsule (20 mg) bid for the treatment period. Study medication will be dispensed in sufficient quantities until the next visit. The no treatment group and all participants in all groups will receive rescue medication by the research pharmacy in sufficient quantities to last them until the next visit. They will be asked to continue their daily pain/mood ratings, and to come back in 3 weeks for an interim visit, bringing back any remaining study medication at that time which will be accounted for by the research pharmacy.

Visit 4 (week 3): Continuing Assessment (30-45 min).
This visit will be completed entirely by the unblinded monitor; there is no clinical data being collected here – only safety data. All procedures will be performed as described for Visit 3. Adherence will be assessed by pill counting for those on treatment group, and participants will be queried about any side effects experienced. In addition one of the pictures for visit 2, 4, and 5 will be conducted (see section 13.III). Study medication and rescue medication will be dispensed in sufficient quantities until the next visit, as described in Visit 3. They will be asked to continue using the phone/computer app and to come back in 3 weeks for their end-of treatment (final) scan.

- Visit 5 (week 6): End of Treatment/Start of Washout and Final Scan (60-90 min):
Participants will undergo the same brain scanning session that they had on Visit 2, and all questionnaires, AE assessment, and treatment medication adherence procedures will be performed as they were in previous visits. Participants will be asked to stop the study medication (if applicable) and to start the washout period, and they will only be given rescue medication at this visit by the research staff (enough to last them until the last visit). In addition one of the pictures for visit 2, 4, and 5 will be conducted (see section 13.III). They will be asked to continue rating their pain and mood on the app and to return for the final visit in 3 weeks. Note that apart from the scanning session and administration of questionnaires via REDCap, all other aspects of this visit will be completed by the unblinded monitor to aid in the maintenance of the double-blind on the part of the study staff.

- Visit 6 (week 9): Final Visit/End of Washout (30-45 min):
Any changes to health will be documented, and vitals will be collected. A short battery of questionnaires will be administered and participants will be compensated for all app ratings completed during the study.

- Interim periods: During weeks in between visits, participant data will be tracked with the assistance of a smart phone/computer application designed for the study (available through a secure website). Depending upon preference, we will download an app onto participants' phones or give them a link to use on their computers; in the case that a participant does not have a smart phone or easy access to a computer/internet, we will provide him/her with a smart phone that has the app already installed. Participants will be given a login and will be asked to use this application twice a day, morning and night for baseline and washout and right after they take their medication for treatment (if applicable). The app asks them to rate the severity of their pain and their mood on a Likert scale, and probes them as to

whether or not they took their medication. This will allow us to keep track of the stability and magnitude of pain and mood, as well as treatment compliance. To encourage them to keep up with this requirement, each time they submit these answers, they will receive 25 cents. Responses and payments will be logged automatically into a secure database that only study personnel will have access to; if participants miss more than 3 consecutive ratings in a row, research personnel will call or text them to remind them to rate or verify that their app is still working (they are automatically alerted via email by a program designed by the lab). The unblinded monitor designated for this study will check participants ratings bi-weekly to verify that ratings are being completed.

- Follow up: Patients will be asked if they wish to be added to our contact list to participate in future studies of the lab. They will also be asked if they accept to be contacted by phone 3 months and 6 months later to assess the long-term effects of the study intervention on their chronic pain intensity.

5.3 Randomization:

All randomization (and blinding, see next section) will be completed by NUCATS (see study roster in Location 2 for name of personnel). NUCATS will generate two randomization sequences, one for each group (predicted responders, Group A, and non-responders, Group B). This approach will ensure the proper 3:3:1 treatment allocation. We will use a variable block design (size of 5 and size of 10), throughout Phase 2 of the study to minimize temporal bias that can accompany longitudinal scanning studies. We don't anticipate much exclusion after randomization and enrollment based on our previous studies (although screen failures during the run-in are likely due to pain level or pathology lab results, for example. The Phase 2 overall sample size is 210 randomized 3:3:1, therefore n = 90 active treatment (n = 45 responders/non-responders), n = 90 placebo treatment (n = 45 responders/non-responders), and n = 30 no treatment (n = 15 responders/non-responders). We expect an attrition rate of ~33% for a final N = 140.

5.4 Blinding Procedures

We describe this study as a 3-arm randomized controlled trial in which two treatment arms are double blinded and the third arm consists of a no-treatment group that is partially unblinded to only the unblinded monitor (who will be unblinded to treatment arm but blinded to treatment identity). Other than this person, all the remaining personnel conducting the study, collecting study endpoints, and analyzing data, including the PI, will be blind to the allocation of participants to study arm, response prediction, and treatment. All pills will be identically encapsulated to ensure blinding for study participants who receive treatment. All pills will be identical in size but there will be two colors of masking encapsulation – blue and bi-colored. This is to help the participant remember to take two different tablets (naproxen/placebo and omeprazole/placebo) at each time and thus reduce the possibility of ingesting two identical pills. The only person who will know which capsules contain active vs placebo will be the unblinded pharmacist responsible for ordering the medication, re-encapsulating the agent, filling the numbered medication vials with the appropriate drug and number of capsules, and handling drug accountability. This person will have no other involvement with study staff or be involved with any study procedures. Unmasking should not be required during the study. If allocation assignment needs to be made available, this will be done based on the circumstances outlined above. If there should be a question regarding proper allocation of treatment product, it would be possible to ascertain placebo from active drug product by opening the treatment capsules and determining if there were an enclosed tablet present. This will be prevented by sealing of all capsules prior to their being placed in treatment vials for dispensing. As mentioned above, the blinded assessor inquiring about medication compliance and adverse events will remain blinded to the treatment arm as the other study staff are, but will not be blinded to treatment versus no-treatment group assignment.

Randomization and drug allocation based on this scheme will be completed by NUCATS and Northwestern's Research Pharmacy, respectively, to ensure blinding. A pharmacist not involved in any other part of the study and without access to study data will be responsible for dispensing

the study medication into bottles and labeling these vials with the PIDs according to the design implemented and drug accountability for both rescue and study agents. The randomization list will be maintained by the pharmacy and be made available to the study PI and study physician only in case of emergency. Un-blinding will only occur if knowledge of the treatment arm would be essential for the safety of the participant. None of the study staff will have access to the randomization list and all study supplies will be identical in appearance other than the PID. All study staff, including the statistician, will remain blinded until database lock. Un-blinding will not take place until the end of the study when the final neuroimaging contrasts will be performed. Preliminary analyses of the data will also be conducted in a blinded fashion using an automated method in which all participants are processed in the same way. An initial platform of analyses including pre-processing, regressors for spontaneous pain episodes, and brain connectivity during resting states can easily be created while remaining blind to the intervention. These preliminary analyses will be first be re-coded and scrambled by someone in the lab who has no other connection to the study, which thus allows other study personnel using this data to remain blinded during preliminary analysis and throughout the study's entirety. Additionally, since there is a no treatment group, measures to continue the partial blind (on the end of the research team) will be done. For the duration of the study, separate personnel (a designated unblinded monitor) will be involved in organizing participant folders, printing questionnaire responses, evaluating interim responses, adverse events, and medication compliance, and walking with participants to collect their medication. This is to ensure that those collecting and analyzing the data can maintain their blind not only to treatment type but also to whether or not treatment was given. Other than the pharmacist and unblinded monitor, the rest of the study staff will remain totally double-blinded and will only be involved in scanning procedures, and sending questionnaires online.

5.5 Visit Windows

Not all participants will be able to come back for their next visit exactly 7 or 21 days from the previous visit. To account for holidays and individuals' personal schedules, the acceptable window for each visit will be ± 5 days from the target date. This window will also be incorporated into pharmacy ordering and pill counts to ensure sufficient amounts of study medication between visits.

6.0 RESPONSE CRITERIA

Treatment response is defined as a reduction in VAS pain intensity > or equal to 20% from visit 1-visit 2 pain ratings, or by permutation testing for change in pain rating by 0.05 p-value. Such individuals are considered treatment "responders," whereas "non-responders" are defined as individuals who experience increased or stable pain levels throughout treatment periods, including reductions in pain **<** 20% of baseline pain intensity.

7.0 ADVERSE EVENTS AND SAFETY ASSESSMENT

7.1 Adverse Event Collection

7.1.1 We will collect all adverse reactions reported for all treatment groups. We collect all AEs (even colds and coughs or any preexisting condition that may have worsened) regardless if they are related to the study or not. Our IRB guidelines state "any change in clinical condition of the participant obtained upon interaction with the participant during the visit or interval, related or unrelated to the study. Health status will be elicited by asking the participants if there has been any change in their overall health or health status rather than asking specifically regarding predefined conditions (open-ended questioning)".

7.1.2 All AEs will be reported to Dr. Thomas Schnitzer, the study physician, for review and appropriate follow-up.

7.2 Adverse Event Monitoring

Adverse event data collection and reporting, which are required as part of every clinical trial, are done to ensure the safety of subjects enrolled in the studies, as well as those who will enroll in future studies using similar agents. Adverse events are reported in a routine manner at scheduled times during a trial. Additionally, certain adverse events must be reported in an expedited manner to allow for optimal monitoring of patient safety and care.

All patients experiencing an adverse event, regardless of its relationship to study compound/drug, will be monitored until:

- the adverse event resolves or the symptoms or signs that constitute the adverse event return to baseline;
- any abnormal laboratory values have returned to baseline;
- there is a satisfactory explanation other than the study compound/drug for the changes observed; or
- death.

The reporting of adverse events, serious adverse events and unanticipated problems will be done according to the guidelines of the Northwestern University IRB and the FDA*. As of August 20, 2007, Northwestern University IRB requires immediate filing of internal or external adverse events reports, or safety reports only if they have been determined by the Principal Investigator to contain a report of unanticipated problems involving risks to subjects or others. NU considers unanticipated problems, in general, to include any adverse event, incident, experience, or outcome that meets all of the following criteria: (1) Unexpected (in terms of nature, severity, or frequency) given: (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied. 1. The known or foreseeable risk of adverse events associated with the procedures involved in the research that are described in: a) the protocol-related documents, such as the IRB-approved research protocol, any applicable investigator brochure, and the current IRB-approved informed consent document; and b) other relevant sources of information, such as product labeling and package inserts; or 2. The expected natural progression of any underlying disease, disorder, or condition of the subject(s) experiencing the adverse event and the subject's predisposing risk factor profile for the adverse event. (2) Related or possibly related to participation in the research (in this guidance document, possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and (3) Suggests that the research places subjects or others at a different or greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

NOTE:
The following events are considered a serious adverse event and would place subjects at a greater risk of harm:

- *results in death;*

• is life-threatening (places the subject at immediate risk of death from the event as it occurred);
• results in inpatient hospitalization or prolongation of existing hospitalization;
• results in a persistent or significant disability/incapacity;
• results in a congenital anomaly/birth defect; or
• based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition (examples of such events include allergic bronchospasm requiring intensive treatment in the emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse).

Unanticipated problems involving risks to subjects or others should be reported to the IRB within 10 working days (unanticipated deaths of subjects enrolled at NU or Affiliates need to be reported within 24 hours).

All adverse events deemed to be serious, both unexpected and expected, will be reported to the medical monitor.

The medical monitor (Dr. Thomas J Schnitzer) is required to review all unanticipated problems involving risk to volunteers or others, serious adverse events and all volunteer deaths associated with the protocol and provide an unbiased written report of the event to the FDA*. The medical monitor will comment on the outcomes of the event or problem and in the case of a serious adverse event or death comment on the relationship to participation in the study. The medical monitor will also indicate whether he/she concurs with the details of the report provided by the study investigator. Reports for events determined by either the investigator or medical monitor to be possibly or definitely related to participation and reports of events resulting in death will be promptly forwarded to the FDA MedWatch Online Reporting System. Note that since the study is not being conducted under an Investigational New Drug Application (IND), mandatory reporting of safety information to the FDA itself is not required. Instead, voluntary reports of adverse events observed or suspected for human medical products will be filed in the online system specified here.

A summary table of adverse events collected will be submitted at least annually to the Northwestern IRB. Additionally, NCCIH will be informed of serious and non-serious adverse events according to the requirements outlined section 6.2.1 below.**7.2.1. Reporting of SAEs**

SAEs that are unanticipated, serious, and possibly related to the study intervention will be reported to the Independent Monitor, IRB, and NCCIH in accordance with requirements.

- Anticipated or unrelated SAEs will be handled in a less urgent manner but will be reported to the Independent Monitor, IRB, NCCIH, and other oversight organizations in accordance with their requirements.

- Unexpected fatal or life-threatening AEs related to the intervention will be reported to the NCCIH Program Officer within 7 days. Other nonserious and unexpected AEs related to the intervention will be reported to the NCCIH Program Official within 14 days.

7.3 Unblinding Procedures

Unblinding the study therapy is not commonly necessary but may be done if required to ensure a subject's safety. In most cases, the unblinding will be part of managing an SAE, and will be reported with the SAE. In cases where unblinding was not associated with an SAE, such actions will be reported in a timely manner (e.g., notification of IRB within 24 hours by phone or fax, followed by a written narrative of the event within 48 hours.). Otherwise, un-blinding will not be done until each phase of the study is complete (that is, when Phase 2 is finished running all enrolled participants, we can unblind the data).

7.4 Stopping Rules/Intervention Discontinuation

This study will be stopped prior to completion if: (1) the intervention is associated with adverse effects that call into question the safety of the intervention; (2) difficulty in study recruitment or retention will significantly impact the ability to evaluate the study endpoints; (3) any new information becomes available during the trial that necessitates stopping the trial; or (4) other situations occur that might warrant stopping the trial.

8.0 STATISTICAL CONSIDERATIONS

8.1 Summaries of Design, Endpoints, and Analysis

8.1.1 Phase II: Study Design/Study Endpoints

Enroll and randomize 220 CBP patients into the study. Stratify into placebo responders and non-responders based on brain scan results at entry. We anticipate that about 50% of the patients will be placebo responders. All participants are randomized so that 40 receive placebo treatment, 40 active medication, and 20 no treatment. If Gender Supplement is awarded then randomization is slightly different: 60 receive placebo, 60 active medication, and 20 no treatment.

We assume that placebo responders and non-responders will show differential interaction with active medication treatment. We also expect to distinguish the four groups based on brain activity at the end of the trial, and show close correspondence between predicted and actual outcomes regarding placebo responses. Additionally, placebo non-responders should show a robust medication response, especially in comparison to the placebo non-responders receiving placebo treatment. Brain activity contrasts are done as a two-way (treatment groups) repeated measures (time: start vs. end) ANOVA (2RM-ANOVA). This is the procedure we implemented recently in a longitudinal neuroimaging study of pain chronification (Baliki et al., 2012). Post-hoc comparisons then reveal: 1) A contrast of brain activity at end of treatment between placebo non-responders with and without medication treatment to identify brain activity for bottom-up modulation of chronic pain. 2) Brain regions related to chronic pain are identified as areas commonly decreased with placebo treatment for placebo responders and medication treatment for placebo non-responders. 3) Top-down placebo and bottom-up medication effects are distinguished by identifying regions that distinctly increase in activity for placebo and medication treatments based on contrasts for the same groups. 4) The no treatment group brain activity is used as a higher-level contrast, which effectively corrects for this confound.

8.1.2 Sample Size and Accrual

Statistical power can be estimated based on the Cohen's d effect sizes for differences in pain with 6 weeks of treatment. For responders, based on our preliminary results, we anticipate a mean decrease of 2.5 units on a 0-10 scales with an estimated SD of 3, which results in an effect size estimate of 0.83. In non-responders, the mean decrease in pain is negligible and we do not expect to have enough power to detect this.

Power analyses in G*Power 3.1.3 indicated that we will have ample power to detect pre-to-post changes within a group; with an estimated effect size of d = 0.8, power would exceed 95% with a sample of 23 participants. In terms of a between-group comparison, assuming an effect size estimate of d = 0.8 across groups, power would exceed 95% for a sample size of n = 42 per group. Thus, the total sample size of 210 would provide for adequate power, even accounting for

potential dropout and/or lower-then-expected effect sizes. Assuming that we recruited 70 participants per group, for example, would mean that we could detect between-group effects as small as d = 0.5 with power exceeding 80%.

Power analysis for gender: The preliminary gender analyses from phase 1 subjects provide the means to calculate the power necessary for detecting gender effects in placebo propensity. The original sample sizes from phase 1 were based on treating gender and age as covariates of no interest. Based on an anticipated medium-sized effect using Cohen's conventions (Cohen, 1992), calculations in chi2power in Stata indicated that for n=82 and for alpha = 0.05 we obtain power = 0.31. Instead if we double the number of subjects then we reach adequate detection power: assuming that males have 30% while females 50% placebo incidence rate, for alpha = 0.05 and n=160 we obtain just adequate power = 0.74. Therefore all data from phase 1 and 2 will be combined to assess effect of gender on placebo response.

Our previous fMRI results show that 20 per group should be adequate given the preliminary results and earlier studies. Also, 20 per group allows for 80+% statistical power for effect sizes of 1 SD difference between groups. For DTI and T1 studies our earlier studies indicate that 20/group for within-subject contrasts is adequate but may be just at the limit for whole-brain contrasts for detecting between-group differences. We can overcome this obstacle by using targeted analyses of relevant brain areas. For example, simply removing the cerebellum and occipital cortex voxels from such analyses results in improving on multiple comparison cost by a factor of 2.

The results from Phase 1 affirm the above power calculations. Moreover they indicate that increasing the n for each of the treatment groups by 50% (as proposed in the gender supplement application) can lead to identifying effects that currently remain either non-significant or borderline significant.

8.2 Data Analysis Plans

Summary: For brain imaging contrasts, fMRI results show that 20 per group should be adequate given the preliminary results and earlier studies. For DTI and T1 studies our earlier studies indicate that 20/group for within subject contrasts is adequate but may be just at the limit for whole brain contrasts for detecting between group differences. In **Phase 2/Aim 2**, we hypothesize that brain parameters will predict strength of treatment response among the placebo stratified group. The n= 20 per group provides adequate sample size for effect sizes of about 1.0.

Given the robust results we have seen already in Phase 1, experimental design and data collection and analysis methods will closely follow the methods we used in Phase 1. To this end, brain imaging data collection details will be identical in Phase 2, all preprocessing and quality control pipelines will remain the same and the same modality comparisons performed in Phase 1 will also be used in Phase 2. Moreover, again we will use a blinded data analysis approach, where for each analysis modality the blinded assessor (Dr. Huang) is not involved in any patient interaction throughout the course of the study and will provide three codes for responders and non-responders one of which is the correct result. This forces all analysis to be done across all three codes and the true code is unraveled only when final results are available for all three codes. This approach is more burdensome however it protects against bias and also reveals false positives (for example figure 7 in report). We have employed this strategy for phase 1 results.

Given the results from Phase 1 we have decreased the number of personality related questionnaires that failed to show even borderline relationships with placebo response. In addition, we have extended the washout period to three weeks, as in Phase 1 a one week wash-out was not long enough. Since the two secondary aims of Phase 2 are to show placebo and active drug interaction and persistence of clinical placebo response, we monitor all participants over a 12-week treatment (or no-treatment) period. This design provides us with all the same contrasts that we have available in Phase 1, in addition to looking at placebo propensity and response in relation to active treatment.

As power analysis shows that gender effect will require all data from Phase 1 and 2, we will combine outcomes from both phases to contrast prevalence of placebo response as a function of gender. If this hypothesis is validated then we perform exploratory analyses to distinguish between both brain and personality differences by gender.

For the language analysis, It has previously been shown that language can capture subtle changes and differences in a person's physiology and personality, and in some cases, language use can even be predictive of someone's future neuropsychological state (Bedi et al., 2015) Given chronic pain's dependence on an individual's neurology and psychology, we hypothesize that language use (specifically in the form of free speech) in chronic back pain patients will be able to not only track treatment response over the duration of the study but also predict patient's propensity to respond to placebo.

In order to study participant's language in time, we will record patient interviews at 4 points during the study (visits 1, 2, 4, and 5) using two different methodologies. At visit 1, we will utilize the first methodology and conduct a semi-structured open-ended baseline interview consisting of primary questions: The questions themselves are taken from sections of the exit interview utilized in the Phase 1 of the study (exploratory aim) and can be found on pages 45-46; the choice of questions is based on preliminary results from Phase 1 showing that the average semantic similarity of patient interviews to 4 different concepts of interest were able to differentiate previous placebo responders from non-responders at the end of the study (Berger et al, in preparation). In Phase 2, our goal is not only to differentiate responders from non-responders (and validate the preliminary results), but also to *predict* responders from non-responders at the beginning of the trial using language. Interviews will be audio-recorded and later transcribed.

To control for inherent interview confounds (such as interpersonal interaction effects or attentionally-biased statements due to pain-related questions) as well as identify how a patient's speech changes over time as a consequence of their pain intensity (and related treatment effects), for visits 2, 4, and 5, we will use a second methodology to study participant's language. In these visits, we will ask patients to describe 1 out of a set of 3 pictures; these pictures will be selected randomly for each visit for all participants and no picture will be presented more than once per person. The pictures utilized have been selected from a set of validated, standardized measures used in the fields of psychology and linguistics to commonly study both divided attention (in autism and ADHD) and speech pathologies (in aphasias, Parkinson's disease, and Alzheimer's) (Carragher et al., 2015; Forbes-McKay & Venneri, 2005) each picture has a main scene with multiple actors, objects, and potential scenarios that a person can attend to and talk about. These pictures are being utilized in this study for four reasons: (1) they provide a language prompt that is not biased by either the topic of pain or by interviewer/interviewee personal dynamics, (2) they have been shown to pick up syntactic and semantic differences in language related to attention and speech effort (these aspects are important for our patients whose attention is constantly divided between the outside world and their continuous background pain), (3) there is a large body of previous speech samples from healthy participants and patients with various ailments that might be able to be used for standardized comparisons, and finally (4) the pictures are consistent enough in features while still being different, making them ideal to test over time (and therefore will allow us to correlate speech to pain metrics and other objectives before, during, and after treatment). Patients will be asked to describe each picture in as much detail as they can

Details:

8.2.1 Pain Response Assessment**:** Phone app or computer pain ratings, NRS and pain memory will be used as in Phase 1 as main pain-related outcome measures. In addition pain related questionnaires may differentiate between placebo analgesia and treatment analgesia. Also the time course of change in these pain parameters can be tested whether they differentiate between the 4 treatment groups.

8.2.2. Resting state: During the resting state protocol, participants are asked to keep their eyes open and let their minds wander during the 10 minute scan. We use graph theoretical analyses of

functional resting state to assess the treatment on large-scale brain architecture. Phase 1 results use this approach and show that brain functional connectivity predicts placebo response. Several additional analyses can be used from resting state data to extract the topological properties of graph networks such as clustering, global efficiency, maximum modularity, and between-ness centrality (for detail see (Achard et al., 2012)). Brain networks identified and validated as reflecting placebo propensity can then be explored regarding their interaction with treatment, both as predictors and as responses.

8.2.3 and **8.2.4**: Fractional Anisotropy (FA) and Probablistic Tractography: Both of these techniques are applied to the DTI scans that will be collected at the beginning of each part of the study to examine white matter structural integrity and connectivity. FA is an index of coherence of the orientation of water diffusion along a tract and is a measurement of overall tract integrity. FA is calculated voxel-wise for each participant over the whole-brain white matter skeleton, averaged over all participants in each group, and extracted to contrast between groups.

The Phase 1 analysis did not show a significant difference in FA relative to placebo response. This may be due to insufficient power, which can be tested in the larger cohort when we combine Phase 1 and Phase 2 DTI data. Given our earlier paper (Mansour et al., 2013) and the one from another group (Stein, Sprenger, Scholz, Wiech, & Bingel, 2012), white matter tracts may still be a strong predictor of functional brain properties and behavioral response related to the placebo effect. We will also use this approach to examine white matter connectivity both for Phase 1 and Phase 2 data. Additionally, we will also calculate radial and axial diffusivity values from this method. In contrast, probabilistic tractography is a seed-based measurement looking at structural connectivity (anatomical connections) between ROIs as a function of group. Direction of white matter patterns are calculated beginning at one seed in the mean FA skeleton and moving a small distance in the estimated direction of the next seed over several iterations until the tract is terminated; connectivity strength between ROIs can then be compared between groups. We have yet to perform this type of analyses for Phase 1 specific brain regions.

NODDI results pending—will attach once Etienne completes final analysis

8.2.5. Subcortical Shape and Volumetric Analyses: The Phase 1 results show that limbic brain hemispheric asymmetry is a predictor of placebo propensity. We will use the same measure to validate this result in Phase 2, using both FSL and Freesurfer measures. So far we only examined this unitary measure and have refrained to explore other subcortical shape and volume properties. With increased power we can begin such explorations, and test their relationship to relevant personality measures.

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8.2.6: Personality Analysis: The dimensionality of the self-report items will be investigated using standard psychometric techniques to ensure that sets of items are sufficiently unidimensional and reliable. The primary test of whether scores from self-report questionnaires can predict treatment response can be investigated using logistic regression. The logistic regression model will be used to discern self-reported questionnaire items (MAIA and ERQ) in context of TOPPP (Tool for Placebo Propensity Prediction).

Phase 1 results identify a robust simple model based on personality that predicts placebo. We will use this or some small variant as our primary personality model to be validated in Phase 2. Additionally, we have kept some other questionnaires that should trend in being predictive and we can test their contribution in the larger cohort in Phase 2.

8.2.7: Predictive Model/Classifier from Brain/Questionnaire Parameters:
The final model from Phase 1 will be used to categorize participants into responders and non-responders. The mathematical details can be found on Page 10, and the identification will be a 1:1 ratio as mentioned in section 5.2.1.This then provides a robust validation for the generalizability of the model.

8.2.8: Language/Interview Analysis:

We will record patient interviews over 4 visits (visits 1, 2, 4, and 5). The first will be a short interview consisting of questions found on pages 44-45. In the remaining visits we will ask patients to describe 1 of a set of 3 pictures (randomly selected for each visit.

All audio and text files will be de-identified with the participant's subject id. Transcripts will be pre-processed according to standard Natural Language Processing (NLP) procedures, including parsing, lemmatizing, and stemming the data. Pre-processed, tokenized text will undergo basic language analyses including calculations of verbosity, unique vocabulary, lexical diversity, and other syntactic and morphological parameters (Hess et al., 1984) that can be used as features of interest or as general quality control measures.

For more in-depth analyses, text data will be converted into numerical data where each word is represented as its alphabetized index in the dictionary. These enumerated data will be fed through latent semantic analysis (LSA) to reduce the dimensionality of the data and transform the interviews into a vector space that can be then quantified in numerous ways (Landauer et al. 1997), including linguistic feature extraction based on singular value decomposition (SVD), calculation of semantic similarity (distance) to words of interest, and sentiment analyses, among others. These morphological, syntactic, and semantic language features will be used to (a) validate previous language results from Phase 1, (b) build additional multivariable models of placebo propensity based on language, (c) identify and quantify relationships between language and the neuroimaging and personality markers of placebo response, and (d) correlate changes in language with changes in pain quality and intensity in time before, during, and after pill treatment.

9.0 STUDY MANAGEMENT, DATA COLLECTION, AND QUALITY ASSURANCE

9.1 Institutional Review Board (IRB) Approval and Consent

It is expected that the IRB will have the proper representation and function in accordance with federally mandated regulations. The IRB should approve the consent form and protocol.

In obtaining and documenting informed consent, the investigator should comply with the applicable regulatory requirement(s), and should adhere to Good Clinical Practice (GCP) and to ethical principles that have their origin in the Declaration of Helsinki.

Before recruitment and enrollment onto this study, the patient will be given a full explanation of the study and will be given the opportunity to review the consent form (see section 9.2). Each consent form must include all the relevant elements currently required by the FDA Regulations and local or state regulations. Once this essential information has been provided to the patient and the investigator is assured that the patient understands the implications of participating in the study, the patient will be asked to give consent to participate in the study by signing an IRB-approved consent form (see 13.I).

Prior to a patient's participation in the trial, the written informed consent form should be signed and personally dated by the patient and by the person who conducted the informed consent discussion.

9.2 Data Management and Monitoring/Auditing

Participants' safety will be closely monitored by the site clinical investigator and the principal investigator. Careful, periodic assessment of all safety data will be undertaken. An inclusion/exclusion criteria checklist will be reviewed for each subject enrolled to ensure that only appropriate subjects are included. Adverse events will be collected at each visit and tabulated by the coordinator during the trial. The site and principal investigators will meet on a monthly basis to review these data. Those that are unexpected and considered related will be reported to the IRB immediately. An annual report of study progress and adverse effects will be made. A detailed draft Data and Safety Monitoring Plan has been developed and is included below in section 13.V. This will be amended as needed and submitted to the Northwestern IRB prior to the accrual of any participants.

9.3 Quality Assurance and Training

Lab members that previously participated in the acquisition of neuroimaging data will be responsible for collecting data at Northwestern University. All of these members have gone through various kinds of training, including but not limited to Protection of Human Subjects and HiPAA online courses, ethics training, collection and shipping of biological specimens, study management classes provided by the NU IRB, and MRI scanner operation training. All lab members that will be interacting with participants and collecting data have all be approved by the IRB as authorized personnel.

Quality control will be ensured throughout preprocessing of the imaging data after each scanning sessions. The metrics that will be assessed for quality control are head movements, scanner artifact, signal to noise ratio, and visual inspection of the images (most of which is done through an automated pipeline designed by our lab). All data will be identified with codes to maintain participants' confidentiality and managed by NUCAT who is responsible for the randomization of the participants. IRB and NCCIH will be informed in case of protocol deviation.

9.4 Data Collection and Forms

All data collection will be done by IRB-approved authorized research personnel (see section 8.3 above). Data in this case is in the form of PHI, questionnaire answers, interview answers, and scans. Participant data (such as PHI) are recorded on paper (stored in coded binders, one per participant) and recorded online (all questionnaires) in a format created by the study team. Paper data is stored in a locked cabinet in a locked room that only study personnel have access to. Online questionnaire data is also automatically coded when participants begin to answer the forms, and answers are stored in a secure database (NUCATS REDCap database, which was recommended by NIH) that is password protected.. Data entry into REDcap will be completed by staff members conducting the visit. Audio recordings from interviews are coded at the start of the interview and are uploaded into coded folders that are password protected and stored in a secure database that only specific personnel have access to. Audio recordings will be kept permanently in the secure database and will have all potential identifying information removed prior to uploading onto the server. Scans collected from the MRI are burned on CDs or DVDs at the end of the session (using coded PIDs) and kept in the study binder (in a locked room). When this scan data is uploaded, it is put on a secure server. All of this confidentiality information can now be found in section 9.3. Note that in most instances, case report forms (CRFs) will not be used as source documents. REDCap access will be limited to only visit 1 to ensure documentation of consent and safe blood levels.

10.0 PARTICIPANT RIGHTS

10.1 IRB Review

This protocol and the informed consent document, as well as any subsequent modifications, will be reviewed and approved by the Northwestern IRB before beginning the study.

10.2 Informed Consent

A signed consent form will be obtained from each participant. For participants who cannot consent for themselves, such as those with a legal guardian or power of attorney, this individual must sign the consent form. The consent form will describe the purpose of the study, the procedures to be followed, and the risks and benefits of participation. A copy will be given to each participant or legal guardian and this fact will be documented in the participant's record (i.e., we make a copy of the signed consent form for our study records). An example of an informed consent document can be found in the Supplements and Appendices section, 13.I.

10.3 Confidentiality

Any data, specimens, forms, reports, audio recordings, and other records that leave the site will be identified only by a participant identification number (Participant ID – PID) to maintain confidentiality. Audio recordings will be stored on our database and will not be destroyed. All records will be kept in a locked file cabinet in a locked room that only specific study personnel have access to. All computer entry and networking programs will be done using PIDS only, and they will be done using a secure server. Access to this data is also password protected and shared only between specific study personnel. Information will not be released without written permission for the participant, except as necessary for monitoring by IRB, the FDA, the NCCIH, and the OHRP.

10.4 Study Discontinuation

As part of their duties to ensure that research participants are protected, this study may be discontinued at any time by the IRB, the NCCIH, the OHRP, the FDA, or other governmental agencies.

11.0 PUBLICATION OF RESEARCH FINDINGS

Any presentation, abstract, or manuscript will be made available to the NCCIH if requested.

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13.0 SUPPLEMENTS/APPENDICES

I. Informed Consent Form Template

Northwestern University
Department of Physiology

Consent Form and HIPAA Authorization for Research
Second Phase

PROTOCOL TITLE: Brain mechanisms for clinical placebo in chronic pain

PRINCIPAL INVESTIGATOR: A. Vania Apkarian, Ph.D.

SUPPORTED BY: National Institutes of Health, NCCIH

Introduction

You are being asked to take part in a research study. This document has important information about the reason for the study, what you will do if you choose to be in this research study, and the way we would like to use information about you and your health.

What is the reason for doing this study?

You are asked to take part in this study because you are a person over the age of 18 who has experienced low back pain for more than 6 months. The purpose of this study is to see how pain is represented in the brain in people who have pain relief with placebo (a sugar pill) treatment, as well as to understand the effects of different treatments on the body and on the brain. We want to study your back pain for 12 weeks, including the characteristics of your pain, and do brain scans using a non-invasive brain imaging technique called functional magnetic resonance imaging (fMRI).

What will you do if you choose to be in this study?

The study requires 6 visits spread out over 12 weeks. You are asked to participate in research that compares placebo with a standard of care drug, a combination of one naproxen capsule (500mg) and one omeprazole capsule (20 mg) taken twice daily, two FDA-approved drugs for use as investigational agents in this study. If you agree to participate. Please know that this is a double-blinded study, which means that neither you nor the study doctor nor the study staff will know whether you are receiving drugs or placebo. However, if there is a safety issue, the study doctor can get this information when warranted. Randomization means you will be randomly assigned to study drugs or placebo based on chance, like a flip of a coin. Neither you nor the researcher chooses your assigned group. You may be assigned to a placebo group, an active drug (naproxen and omeprazole) group, or a no-drugs group (you will not receive any pills except Rescue Medication).

If you consent to participate, you will be asked to come to the following location:

710 N. Fairbanks Ct
Olson Pavilion
Center for Translational Imaging (CTI), located in the basement (LC 0-255)
Chicago, IL 60611

All scanning visits will take place at the location listed above.
Northwestern University, Feinberg School of Medicine

10th floor Abbot Hall, 710 N Lake Shore Dr
Chicago, IL 60611

All other visits will take place at the location listed above.

Visit 1 (week -3): Screening visit (90 min).
If you agree to participate, you will be evaluated with inclusion/exclusion criteria and complete the informed consent documents. A medical/pain history will be taken and physical exam will be completed by a physician and you will be asked to rate your current back pain intensity. You will complete a set of 10 questionnaires that will ask you about your health and medical history, past and current pain levels, personality, and emotions. You will be allowed to take breaks and walk around during this time so that you don't get tired while filling out questionnaires. Finally, you will have your blood drawn for screening purposes including to see if your kidneys and liver are functioning as they should (we will take 40 mL or about 8 teaspoons). You will be asked to return in 2 weeks for baseline magnetic resonance imaging scans. You will be asked to discontinue your current pain medications 14 days prior to Visit 2 and take only the rescue medication ("rescue" medication that is also known as acetaminophen/Tylenol ®), given for pain during this time (see below) – this is so that we can assess your baseline amount of pain. You will be informed that you may be randomized in the placebo group and/or the no-treatment group (Visit 3) once you qualify to continue in the study. You must therefore be willing and able to stop taking the medication you take for pain for up to a maximum of 12 weeks during this study. You will be given acetaminophen (500 mg, up to 4 times per day) to take if you require pain relief (as rescue medication), a dose that can be continued throughout the study. You are free to stop your participation if you feel you are not able to deal with the intensity of your pain. If you are randomized to the treatment group (active or placebo) you may receive the anti-inflammatory drug naproxen, since it is known to increase the risk of stomach and intestinal side effects, a combined naproxen/omeprazole drug regimen will be given to you to provide some protection for these types of side effects. You will also be asked questions about your pain and mood in an interview at the end of this visit. This interview will be recorded with a voice recorder.

Visit 2 (week -1): Baseline Scan (90 min).
You will rate your pain intensity, complete questionnaires, and undergo brain scanning (anatomical and functional scans). You will receive medication, which you can use if the pain becomes too much to handle (500 mg four times per day maximum). The researcher will ask you about how often you used the "rescue" medication and any changes in health you may have experienced since last visit. You will also be asked to describe a picture and will be given up to 5 minutes to describe the picture given. This will be recorded on a voice recorder.

Visit 3 (week 0): Start of Treatment Period and Randomization (30-45 min).
You will rate your pain intensity and complete questionnaires. You will be randomized into either a drug (placebo *or* naproxen and omeprazole) treatment group or no treatment group; if you are assigned to a treatment group (active or placebo), neither you nor the clinical coordinator/assistant will know which group you are in. Enough medication will be given to you to last until the next visit. The placebo group will receive two placebo capsules twice daily and the active drug group will receive one naproxen capsule (500mg) and one omeprazole capsule (20mg) twice daily (morning and night) for the treatment period. The medication (Naproxen or Placebo) needs to be taken with at least one full glass (8 oz) of water and the other medication (Omeprazole or Placebo) should be taken one hour before a meal. The researcher will provide the study medication; if you were randomized into the no treatment group you will only receive rescue medication. The researcher will ask you about how often you used the "rescue" medication and any side effects you experienced since Visit 2 took place. Additional "rescue" medication will be given to you, and if you are in one of the treatment groups.

Visit 4 (week 3): Continuing Assessment (30-45 min).
The procedures described for Visit 3 will be repeated during this visit. The researcher will ask you about how often you used the "rescue" medication and any side effects you experienced since Visit 3 took

place. As well, the researcher will ask you how often you took the study medication (if in a treatment group) and document the total pills you ingested. You will also be asked to describe a picture and will be given up to 5 minutes to describe the picture given. This will be recorded on a voice recorder.

Visit 5 (week 6): End of Treatment/Start of Washout and Final Scan (60-90 min):
The procedures described for Visit 2 will be repeated during this visit. The researcher will ask you about how often and reliably you took your medication (if in a treatment group), as well as how often you used the "rescue" medication and any side effects you experienced since Visit 4 took place. You will only receive the "rescue" medication for the upcoming 3 weeks. You will also be asked to describe a picture and will be given up to 5 minutes to describe the picture given. This will be recorded on a voice recorder.

Visit 6 (week 9): Final Visit/End of Washout (30-45 min):
You will return to complete questionnaires but no brain scans will be done. The researcher will ask you about how often you used the "rescue" medication and any side effects you experienced since Visit 5 took place. If you are in one of the treatment groups, you will be asked to return all of your study medication and rescue medication at this time, and all treatment will be stopped at this visit.

Interim Activities
For the duration of the study, you will be asked to rate your pain and mood twice a day (even in between visits). This will be done with an electronic application that we will train you how to use. We will download an application onto your phone or give you a link to use on your computer; if you do not have a smart phone or easy access to a computer/internet, we will provide you with a smart phone that has the application already installed. You will be compensated for your responses. Please note that if you fail to rate your pain too many times in a row, you may be dropped from the study.

fMRI
This study uses functional magnetic resonance imaging (MRI) to look at the brain. Functional magnetic resonance imaging is a type of brain scan that uses magnetic fields and radio waves to make an image of changes in blood flow in your brain while you do certain tasks.

In order to make sure the MRI procedure will be safe, you will be asked to fill out a screening form before starting the study. It is important that you tell the researchers in this study if you have any history of:

- Metal fragments in your eyes or face.
- Implantation of any electronic devices such as (but not limited to) cardiac pacemakers, cardiac defibrillators, cochlea implants or nerve stimulators.
- Surgery on the blood vessels of your brain or the valves of the heart
- Claustrophobia (fear of enclosed places)
- Body piercing or tattoos

You will be given instructions outside the MRI scanner about the scanning. Next you will be asked to lie still on the MRI patient table and your head will be placed in a specially-designed head holder. Your head will be cushioned by a firm foam pillow. The table will then slide into the enclosed space of the MRI scanner. Some people feel tired, uncomfortable or claustrophobic (afraid of small spaces) in the MRI scanner. The MRI scanning session will take around 40 minutes to complete once you are in the scanner.

The information from the MRI scanner is only useful if you are able to complete the whole imaging session, and hold your head very still the whole time. Therefore you will be encouraged to hold as still as possible, and to let the investigators know if you are uncomfortable in any way as soon as possible after the imaging session begins.

The front of the head-holder will be open, which lets you look through a special mirror and be able to see outside of the scanner if you want to. The MRI scanner makes loud banging noises while taking a measurement, so either ear plugs or specially designed headphones will be used to reduce the noise. The researchers will be in communication with you through an intercom system to tell you how the study is going. The earplugs or headphones should not get in the way of communicating with the researchers.

What are some of the possible risks and discomforts?

The risks from the study procedures include the following, some of which may be serious, including the risk of worsening your low back pain condition and related symptoms, especially since you may receive a placebo for up to 12 weeks:

Blood Draw:

The risks of taking blood include pain, a bruise at the point where the blood is taken, redness and swelling of the vein, infection, and fainting.

Study Agents:

The side effects for naproxen include: upset stomach, nausea, heartburn, headache, drowsiness, and dizziness. They also include less common but serious side effects such as: easy bruising/bleeding, difficult/painful swallowing, hearing changes, mental/mood changes, intestinal bleeding, swelling of limbs, sudden unexplained weight gain, change in the amount of urine produced, unexplained neck stiffness, vision changes, unusual fatigue, and liver damage. To minimize the risk of developing gastrointestinal ulcers and indigestion, if you receive naproxen, you will also receive omeprazole.

The side effects for omeprazole (given with a capsule of naproxen) **include**: headache, drowsiness, diarrhea, nausea, stomach pain, and dry mouth. Less common but serious side effects include: dizziness, confusion, fast or uneven heart rate, jerking muscle movements, jittery feeling, muscle cramps, muscle weakness or limp feeling, a choking feeling, or seizure/convulsions.

The side effects for acetaminophen (the "rescue medication") **include**: nausea, rash, and headache. However, acetaminophen may cause liver damage and rarely death due to overdosing and/or mixing with alcohol. Because alcohol interacts with acetaminophen, you should avoid alcohol during this study and/or limit yourself to the equivalent of one beer per day. If you drink 3 or more alcoholic beverages per day, you should tell the study doctor. Liver problems may result from taking acetaminophen.. Early symptoms of liver damage include, but are not limited to, nausea, vomiting, sweating, and general malaise (not feeling well). Subjects should not take more than four 500 mg tablets (rescue medication daily maximum) during a 24-hour period. Regular use of acetaminophen may increase the risk of chronic kidney failure, especially in those individuals with pre-existing kidney disease.

The side effects for placebo include: [relate the side effects relevant for the composition of the placebo] There are no expected side effects other placebo because it contains no active drug.

Scanning:

Risks associated with MRI or fMRI scanning include l an increase in your level of chronic back pain because you will be asked to lie down in the scanner bed for around 40 minutes at a time. You may experience mild discomfort from trying to keep still, or you may feel anxious or claustrophobic (afraid of small spaces) in the scanner. During one of the scans, the scanner may vibrate or be louder than usual. You will always be in contact with a researcher in the scanning room, and he/she can stop the scanning session if you have too much pain to continue.

Some people cannot have an MRI because they have some type of metal in their body. For instance, if you have a heart pacemaker, artificial heart valves, metal implants such as metal ear implants, bullet pieces, chemotherapy or insulin pumps or any other metal such as metal clips or rings, you cannot have an MRI. During this test, you will lie in a small closed area inside a large magnetic tube. Some people are scared or anxious in small places (claustrophobic). The MRI scanner makes loud banging noises while taking a measurement, so either ear plugs or specially designed headphones will be used to reduce the

noise.

The MRI pictures from this study will not be in a form readable by either you or your doctor. Therefore, a copy of the MRI pictures or the results of your individual study will not be given either to you or your doctor. While the MRI pictures in this study are not formally reviewed by a radiologist, if in the course of processing the images we notice any abnormality that would be possibly important to your health we will tell you and a doctor you name.

Questionnaires and Interviews:
Some of the questions asked in the interviews throughout the study are personal and may make you uncomfortable. Some of the questions in the questionnaires may be upsetting or you may be uncomfortable answering them. If you do not want to answer a question or set of questions at any time, you can tell the researcher to skip it/them.

What do I need to know about reproductive health/sexual activity if I am in this study?
If sexually active, both men and women should use an effective method of birth control while taking the study drugs. Barrier contraceptives (condoms or diaphragm) with spermicide, intrauterine devices (IUDs), hormonal contraceptives, oral contraceptive pills, surgical sterilization, and complete abstinence are examples of effective methods. If you or your partner become pregnant while taking the study drugs, it is important that you tell your study doctor immediately. You may have to stop the study drugs. The study drugs have been shown to be harmful to developing fetuses and should only be taken by pregnant women when there is no other alternative and their health care providers have determined that the benefits of taking the study drugs outweigh the risks. Other treatment options will be discussed with you if you stop the study drugs. If you are considered to be postmenopausal, you are not required to use contraception while in this study. Rarely, women considered to be postmenopausal become pregnant. If you suspect that you become pregnant while taking the study drugs, it is important that you tell the study doctor immediately. You may have to stop the study drugs. Other treatment options will be discussed with you if you stop the study drugs.

What are the Possible Benefits for Me or Others?
The possible benefits to you from this study include reduced back pain due to placebo or standard-of-care treatment during the study. Taking part in this study may help scientists to better understand why some people get pain relief from different types of treatments for chronic low back pain. This knowledge can improve daily life and suffering for many people who live with back pain who currently do not experience pain relief from commonly used pain treatments. Ultimately, this research could lead to improved treatment of back pain, you may also benefit from pain relief in the long term, regardless of which group you are assigned to.. If you are randomized in the no treatment group, we will provide most effective study medication at the end of the study for a single 3 week treatment period.

It is important to note, however, that there also may not be any direct benefit to taking part in this study.

What other procedures or courses of treatment might be available to me?
You do not have to take part in this research study. Instead of being this study, you can seek treatment from your family doctor, physical therapist, and pain management specialists. You may request additional information on these resources from the researcher.

Are there any financial costs to being in this study*?*
There are no costs to you for being in this study other than the costs of transportation to and from the study visits..

Travel Expenses:
You will be given assistance, such as parking vouchers, and/or reimbursement for expenses related to travel up to $20 per study visit. If you take public transportation or a taxi you must bring receipts and your reimbursement will be provided to you in cash at the time of your visit. If you drive your own vehicle, you will be reimbursed for gas mileage from your home address to the study clinic and receive a parking voucher for free parking for up to 6hours.. To receive free parking, you must park in the garage at 222 East Huron Street and we will give you a voucher to use that day.

Will I receive payment for participation in this study?

You will get up to $242 for completion of all procedures and study visits in this research study (not counting transportation reimbursement as explained above). Upon completion of each scanning visit (visit 2 and visit 5), you will receive: $50. For the remaining visits (visit 1, visit 3, visit 4, and visit 6) you will be paid $25. You will be paid $0.25 for each time you use the electronic application (maximum of 2 times per day). You will be paid only for the visits and the ratings you complete. You will receive payments either by cash at the end of each visit, or by check that is sent to you in the mail. You will receive a check if you have to end the study early and will receive compensation for pain ratings. If you are paid by check, the Accounting Services at Northwestern University will be given your name, address, and Social Security Number in order to issue a check for your study participation. Study payments are considered taxable income and reportable to the IRS. A Form 1099 will be sent to you if your total payments are $600 or more in a calendar year.

For individuals assigned to the no treatment group who elect to receive treatment after the study is completed and all participants are unblinded. You will be given the option to have the treatment at no cost to you at that time. However, you will not be paid for receiving this treatment. This is optional for those individuals who would like to try the most effective treatment (Active or Placebo). Those interested individuals will be asked to arrive to Abbott Hall to pick up a 3 week treatment supply after the study has ended.

What should I do if I am injured as a result of being in this study?

If you become ill or get an injury or illness as a result of study (medications or procedures), you should seek medical treatment through your doctor or treatment center of choice. You should promptly tell the study doctor about any illness or injury.

Northwestern Memorial Hospital, Northwestern University, and the investigators of this study will not pay for medical care required because of a bad outcome resulting from your participation in this research study. This does not keep you from seeking to be paid back for care required because of a bad outcome.

The coverage for such injury or illness is only available if the Northwestern University principal investigator have decided that the injury/illness is directly related to the study drug or study procedures and is not the result of a pre-existing condition or the normal progression of your disease, or because you have not followed the directions of the study doctor. If your insurance is billed, you may be required to pay deductibles and co-payments that apply. You should check with your insurance company about any such payments.

If I have questions or concerns about this research study, whom can I call?

You can call us with your questions or concerns. If you have any illness or injury during your time on this study, you should call us promptly. You can contact the study Clinical Coordinator (Monday through Friday, 9:00am – 5:00pm at 312-503-2886). For problems arising evenings or weekends, you may call Dr. Thomas Schnitzer at 312-649-2964 (24 hours a day, 7 days a week). Dr. A. Vania Apkarian is the person in charge of this research study. You can call him at 312-503-0404 (Monday through Friday, 9:00am – 5:00pm).

What are my rights as a research subject?

If you choose to be in this study, you have the right to be treated with respect, including respect for your decision whether or not you wish to continue or stop being in the study. You are free to choose to stop being in the study at any time. Additionally, if you are interested, you will have an option to participate in other low back pain studies at Northwestern University.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment to which you are otherwise entitled.

Your participation in this study may be stopped by the investigator without your consent if you do not follow the directions of the study staff. If this occurs, you will be informed by the study staff and will not continue with the remaining visits. You will still be reimbursed for the portions of the study that you have completed.

If you want to speak with someone who is not directly involved in this research, or have questions about your rights as a research subject, please contact the Northwestern University Institutional Review Board (IRB) Office. You can call them at 312-503-9338.

What about my confidentiality and privacy rights?

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Your health information we may collect and use for this research includes:

- Medical history
- Lab tests, or certain health information indicating or relating to a particular condition as well diaries and questionnaires
- Records about study medication or drugs
- Records from brain scans
- Billing information
- Audio recordings

This consent expires on 04/24/2017. After this date, Northwestern University may not gather new information about you, use or disclose your personal health information collected in this study for any purpose other than the research study described in this consent unless Northwestern University obtains permission to do so from you. Illinois State Law permits use and disclosure of your mental health information only to the extent specified in this document.

During this study you may be coming to a Northwestern Memorial Healthcare Corporation entity (for example, Northwestern Memorial Hospital, Prentice Women's Hospital) for research appointments or to get clinical services, such as lab tests, needed for the study. When that happens, you will be scheduled for these services through the NMHC computer system. When a clinical exam or lab is done by NMHC or one of its employees for the purpose of this research study, that information will be kept in both NMHC's clinical records and in the study records.

The following groups of people may give the researchers information about you:

- Authorized members of the Northwestern University and the Rehabilitation Institute of Chicago workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board.
- Clinical affiliates, including but not limited the Rehabilitation Institute of Chicago (RIC), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), Northwestern Lake Forest Hospital (NLFH), and the Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's). Your participation in this clinical trial may be tracked in an electronic database and may be seen by investigators running other trials that you are enrolled in and by your healthcare providers
- Clinical affiliates, including but not limited to Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH), for purposes including, but not limited to, the affiliate's provision of care to you and/or the affiliate's scheduling of appointments and/or billing activities.
- Other University research centers and University contractors who are also working on the study
- Study monitors and auditors who make sure that the study is being done properly, National Center for Complementary and Integrative Health (NCCIH) who is sponsoring the study, and that company's contractors and partners.
- Government agencies and public health authorities, such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings. Furthermore, any audio recordings used in any publications, teaching or scientific meetings will have no identifying information such as your name. The researcher will ask you to refrain from using your name or any other potential identifying information during the recording sessions. In the case, which any recordings have any potential identifying information they will be deleted and we will ask you to perform the audio recording session again. Once the recording is completed a research staff member will upload it to our secure data server, only accessible by research staff, and will then be deleted off the voice recorder.

Unless you revoke your consent, it will expire 04/24/17

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

A. Vania Apkarian, Ph.D.

Northwestern University, Department of Physiology

310 E. Superior Street #7-705

Chicago, IL 60611

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

A copy of this signed consent document, information about this study, and the results of any test or procedure done may be included in your medical records and may be seen by your insurance company.

ClinicalTrials.gov

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

I agree	**I disagree**	
_____	_____	The researcher may contact me in the future to see whether I am interested in participating in other research studies such as Electroencephalogram recording and Saliva collection.

Consent Summary:

I have read this consent form and the research study has been explained to me. I have been given time to ask questions, and have been told whom to contact if I have more questions. I agree to be in the research study described above.

A copy of the consent form will be provided to me after I sign it. A copy of this signed consent document, information about this study and the results of any test or procedure done may be included in my medical record and may be seen by my insurance company.

_____ / _____ Date_____
Subject's Name (printed) and Signature

_____ / _____ Date_____
Name (printed) and Signature of Person Obtaining Consent

Time of Consent _____

II. List of Questionnaires

(A) General Information:
1. MQS - Medicine Quantification Scale – Completed at visit 1

Provides us with a measurement of the amount and kinds of medication they are taking prior to beginning the study

2. MRI Screening Form – Completed at each scanning visit
Makes sure that participants are safe to go into the MRI scanner before each visit
3. NIH Demographics Form – Completed at visit 1
Collects standard demographics – age, gender, race, ethnicity
4. PHI - Patient Health Information – Completed at visit 1
Collects contact information and other standard demographics (such as level of education and annual income), as well as a very basic medical/health history
5. ODI – Oswestery Low Back Disability Index – Completed at visit 1 and visit 5
Collects information about how much pain impacts various aspects of quality of life and how disabled participants feel on account of their pain

(B) Pain-related:

1. PCS - Pain Catastrophizing Scale - Completed at visit 1
Measures how much people worry about their pain and its possible causes (which may tie into the placebo response).
2. MPQ-sf - McGill Pain Questionnaire (short form) – Completed at each visit
Measures location, duration, intensity, and quality/qualia of pain. Allows us to not only track change in pain over time, but also correlate these qualities to brain imaging data collected on the same days.
3. PDt - Pain Detect – Completed at each visit
Provides information about location, duration, intensity, and quality of pain, but does so at different time scales (now, 24 hrs, 1 week) and with more unique time information (fluctuating, intermittent, etc). We can also correlate changes in these scores to brain data.
4. PIC - Patient Impressions of Change - Completed at each visit
One question provides an overall score for the extent to which pain changed (increased/decreased) or remained the same from visit to visit (another way to measure the placebo response).
10. NRS – Numeric Rating Scale – Completed at each visit *(this is a component of many of the questionnaires that we have simply put into one measurement for simplicity; they rate their pain from 0 to 10 with either a sliding bar that gives a number or on a bar with numbers clearly marked)*

(C) Expectation Related to Medication/Medicine Beliefs

1. HCAHQ - Holistic Complementary and Alternative Health Questionnaire- Completed at visit 6
Measures participant's opinions and beliefs about whether alternative/complementary medicinal techniques work and should be used, including questions that subtly ask about the placebo response (e.g., mind-body connection and positive thinking as an important treatment). We can see if beliefs about these types of therapies influence the placebo response.
2. MHLC - Multidimensional Health Locus of Control – Completed at visit 6
Provides information on how well participants believe they themselves (as opposed to medicine or the health care system and/or "luck/fate") are responsible for and in control of their health.
3. TSS – Treatment Satisfaction Survey – Completed at visit 4 and visit 5 (after they have taken all of their medication for treatment period and continuing assessment, respectively
Self-developed 2-question survey that asks participants to rate how satisfied or dissatisfied they are with the study medication and to explain why.

(D) Mindfulness, Interoceptive Awareness, and Emotional Control/Regulation

1. MAIA - Multidimensional Assessment of Interoceptive Awareness – Completed at visit 1
Measures how aware someone is of his/her body and how well they can focus on bodily sensations (such as pain) or distract themselves from these sensations. Such a quality may also link to the propensity to respond or not respond to a placebo. The ability to control awareness or to just be more aware of one's body in general may also link to brain imaging data related to the functional connectivity of the insula and the mPFC.
2. ERQ - Emotional Regulation Questionnaire – Completed at visit 1
Measures how well a person can control his/her emotions (includes reappraisal and suppression of both positive and negative emotions). May correlate with amygdala- or prefrontal region-related imaging data.

(E) Suggestibility
1. MISS - Multidimensional Iowa Suggestibility Scale (we are interested in the Persuadability, Sensation Contagion, and Psychosomatic Control subscales) – Completed at visit 6
Measures the extent to which a participant is/can be influenced by a variety of other external and internal factors. Suggestibility has been shown to influence the placebo response in some previous studies.

(F) Personality and Current Emotional States
1. BDI – Beck Depression Index – Completed during the screening visit
Measures whether someone may or may not be clinically depressed. Because depression can also influence brain states and anatomy, a high BDI score (>=19) is an exclusion criteria for the study.
2. LAQ – Loss Aversion Questionnaire – Completed at visit 1
Measures how sensitive individuals are to a wide variety of potential "losses" in their lives. Our research has shown that people with chronic back pain tend to be more gain sensitive than healthy counterparts (paper submitted to Molecular Pain), which may correlate not only to the presence of pain but also to the propensity to respond to medications (as in less sensitive to lower efficacy medications). LAQ answers may also correlate with NAc, prefrontal, and amygdala brain imaging data.

III. Interview Scripts

Visit 1 Script:

As you know, this is a study about understanding chronic pain. We are really interested in understanding chronic pain and people's responses to medication, with the hope that we will be able to help treat or prevent chronic pain in the future. We are especially interested in how chronic pain impacts people's day-to-day experiences and their quality of life – we think that it is very important to hear from you directly about what your pain is like and how it affects you. We think YOU are an expert on your own pain, so we want to learn from you.

Today I'll be asking you some questions about your life experiences dealing with chronic pain. I would like you to answer them as fully and honestly as you can. There are no right or wrong answers, and you can skip any questions that you don't feel comfortable answering. There is no specific order or time limit, so you can feel free to come back to a question if you need more time to think about it. You can tell me as little or as much as you want to. Some of the questions might be personal to you – if you feel uncomfortable with any question and do not want to answer it, please let me know. The interview will be around 45 minutes, but for some people it may be shorter or longer, depending upon how much we talk.

I will be recording our conversation with this voice recorder. This is to help me remember what we talked about and to be as accurate as possible in reporting what I've heard. When the interview is done, the conversation will be typed out and stored in a secure folder on our server that only myself and my team will have access to. The recording will be deleted from the device so that no one else can listen to it. I will also not use your name in the interview so that your name is not directly connected to the recording. Do you have any questions about this?

Do you have any questions or concerns that you would like to ask before we begin?

---

1. To begin, tell me about your experience with your back pain.

Follow up: How has your pain been recently?
Follow up: How long have you had your pain?

Follow up: What do you think may have caused it?

Follow up: How has your pain changed over time?
Follow ups: What does your pain feel like? What words would you use to describe what your pain feels like right now?
Follow ups: How has your pain changed over the course of the study (in the last 6 weeks)? Was this because of the treatment?

Follow up: Do you see yourself differently because of your pain?

Follow up: What are some things that influence your pain?
Follow ups: What makes it worse? What makes it better?
Follow up: How do you manage your pain? How do you cope with your pain?
Probes: increased/decreased/specific physical activity, sleep quality, body position, medications, faith/spirituality, weather, working, bad day, other distractions including: smoking or drinking, social activities, family, support system, etc…

Follow up: What do you understand about your back? Explain to me how you think your back pain works (what do you think is happening in your body?).
Follow up: Do you think back pain is different for different people?
Follow up: Do you have a family history of chronic pain? Please explain.
Follow up: [*If not]* Do you know anyone else who had/has chronic pain? Tell me more about that/him/her.
Follow up: How do/did they deal with their pain?
Follow up: Did this affect/change how you deal with your pain?

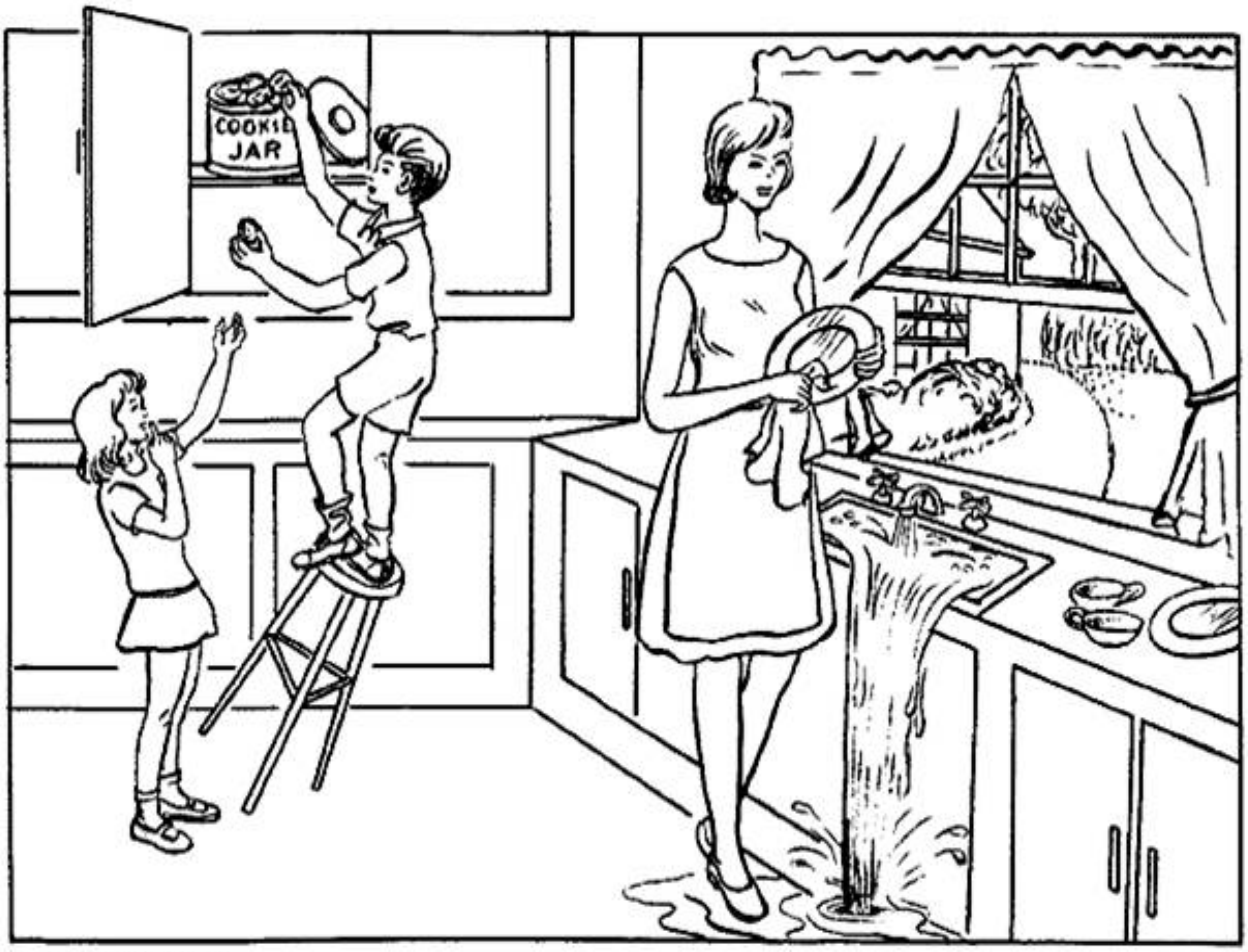
Follow up: How do you think your pain will be a year from now?
Follow up: Why do you say that?
Follow up: Have you ever woken up and thought that the pain was gone?
Follow up: Do you believe your pain will disappear one day?

Follow up: How does your pain affect your mood?
Follow up: Has pain ever made you feel angry?
Follow up: Has pain ever made you feel sad?
Follow up: Has pain ever made you feel anxious?
Follow up: Has pain ever made you frustrated?
Follow up: And now the reverse – how does your mood affect your pain?
Probes: definition of mood, happiness helped alleviate the pain or made it easier to ignore, sadness or anger made it worse,
Follow up: Does pain affect your concentration or decision-making? Tell me more about that.
Follow up: Or your memory? Please explain.

Visit 2, Visit 4, and Visit 5 Scripts:

Participants will be given three pictures (see below) and will be asked to freely explain the picture in their own words. Participants will have at most 5 minutes to explain the picture in their own words before the research personnel terminates the recording. The three pictures will be sorted at random per participant, therefore, picture 1 may be given at visit 5 and picture 3 given at visit 4 for one participant, which can be the different order for another participant.

Picture 1



Picture 2

Picture 3

IV. AE Collection Form Example

ADVERSE EVENT FORM

Brain Mechanisms for Clinical Placebo in Chronic Pain: RO1 AT007987-01A1

Principal Investigator: Dr. A. Vania Apkarian

NORTHWESTERN UNIVERSITY

Subject ID/Initials:

Date Reported	Adverse Event Description	Severity see codes below	Serious (Y/N)	Start Date			End Date			Treatment or Action Taken	Relationship to Study Procedures see codes below	Relationship to Study Drug see codes below	Relationship to Study Device see codes below	CRC Initials	PI Initials	PI Date
				Day	Month	Year	Day	Month	Year							

Severity
Mild 1 - Awareness of Sign or Symptom, but easily tolerated
Moderate 2 - Discomforting Enough to Cause Interference with Usual Activity
Severe 3 - Incapacitating wth Inability to Perform Usual Activity

Serious - Death, life threatening, permanently or substantially disabling, requires or prolongs inpatient hospitalization, or is a congenital anomaly, cancer, or overdose.

Action Taken
1 - None
2 - Medication
3 - Hospitalization
4 - Study Drug Interupted
5 - Study Drug Dose Adjusted
6 - Study Drug Permanently Discontinued

Relationship
1 - Unrelated
2 - Possibly Related
3 - Probably Related
4 - Definitely Related

Version 04.14.2014

Page ____ of ____

V. Data and Safety Monitoring Plan (DSMP)

Data and Safety Monitoring Plan (DSMP)
Independent Monitor

1) Study Identification Information

A) NIH Study Number RO1 AT007987-01A1

B) Study Title Brain mechanisms for clinical placebo in chronic pain

C). Name of Principal Investigator (PI) **Apkar V. Apkarian, Ph.D.**

2) Study Overview

A) This is a randomized, partially-blind clinical trial addressing the topic of placebo mechanisms in management of chronic pain. The overall purpose of this study is to identify brain mechanisms and characteristics of the placebo analgesia response in chronic pain patients (CPP) and utilize them as potential predictors of response to placebo based analgesia.

B) The Data and Safety Monitoring Plan (DSMP) outlined below will adhere to the protocol approved by the Northwestern University IRB.

3) Confidentiality

A) **Protection of Subject Privacy**

During this study, medical history and physical examination will be performed at visit 1 and at regular intervals for various potential aversive side effects. All of the materials collected are for research purposes only, and data will be kept in strict confidence. No information will be given to anyone without permission from the subject. The consent form includes the informed consent statement required by Northwestern University for studies involving human subjects. This statement guarantees confidentiality and identifies the subject as the owner of the information provided. Confidentiality will be ensured by use of identification codes. All data, whether generated in the laboratory or at the scanner, will be identified with a randomly generated identification code unique to the subject.

B) **Database Protection**

The database will be secured with password protection. The informatics manager will receive only coded information that is entered into the database under those identification numbers. Electronic communication with outside collaborators will involve only unidentifiable information. Adverse event reports and annual summaries will not include subject- or group-identifiable material. Each report will only include the identification code.

4) Adverse Event Information

A) **Definition**

An adverse event (AE) is any untoward medical occurrence in a subject during participation in the clinical study or with use of placebo or naproxen/omeprazole. An adverse finding can include a sign, symptom, abnormal assessment (laboratory test value, vital signs, electrocardiogram finding, etc.), or any combination of these.

A serious adverse event (SAE) is any adverse event that results in one or more of the following outcomes:

- Death
- A life-threatening event
- Inpatient hospitalization or prolongation of existing hospitalization
- A persistent or significant disability/incapacity
- A congenital anomaly or birth defect
- An important medical event based upon appropriate medical judgment

B) **Classification of AE Severity**

AEs will be labeled according to severity, which is based on their impact on the patient. An AE will be termed “mild” if it does not have a major impact on the patient, “moderate” if it causes the patient some minor inconvenience and “severe” if it causes a substantial disruption to the patient’s well-being.

C) **AE Attribution Scale**

AEs will be categorized according to the likelihood that they are related to the study intervention. Specifically, they will be labeled definitely unrelated, definitely related, probably related, or possibly related to the study intervention.

D) **Expected Risks**

Naproxen/omeprazole magnesium is used to treat signs and symptoms of osteoarthritis when there is a high risk for stomach ulcer/bleeding. The fact that it contains naproxen (NSAID) increases certain risks including the chance of heart attack, inflammation of the stomach lining, indigestion, diarrhea, or stomach ulcers.

These risks are considered to range from minimal to severe and are addressed in the protocol and consent form.

Dr. Thomas Schnitzer will review adverse effects every four weeks. Any adverse event will be reported to the Northwestern IRB and NIH/NCCIH.

E) AE Reporting and Followup

Please refer to Tables 4, 5, and 6 in DSMP Appendix A for formats for AE data collection and reporting.

F). **SAE Reporting**

SAEs that are unanticipated, serious, and possibly related to the study intervention will be reported to the Independent Monitor, IRB, and NCCIH in accordance with requirements.

- Unexpected fatal or life-threatening AEs related to the intervention will be reported to the NCCIH Program Officer within 7 days. Other serious and unexpected AEs related to the intervention will be reported to the NCCIH Program Official within 14 days.

- Anticipated or unrelated SAEs will be handled in a less urgent manner but will be reported to the Independent Monitor, IRB, NCCIH, and other oversight organizations in accordance with their requirements.

- The medical monitor (Dr. Thomas J Schnitzer) is required to review all unanticipated problems involving risk to volunteers or others, serious adverse events and all volunteer deaths associated with the protocol and provide an unbiased written report of the event to the FDA. The medical monitor will comment on the outcomes of the event or problem and in the case of a serious adverse event or death comment on the relationship to participation in the study. The medical monitor will also indicate whether he/she concurs with the details of the report provided by the study investigator. Reports for events determined by either the investigator or medical monitor to be possibly or definitely related to participation and reports of events resulting in death will be promptly forwarded to the FDA.

G) Data Quality and Management

i. Description of Plan for Data Quality and Management*:*

The unblinded monitor will have access to review all data collection forms on an ongoing basis for data completeness and accuracy as well as protocol compliance. Logs of scanned participants as well as drug dispension and follow-up will be regularly assessed by the unblinded monitor . Data verification will be performed by

someone other than the individual originally collecting the data at interim visits and after study completion. In REDcap, double data entry will be used as a quality assessment measure for paper source documents used as CRFs that will be uploaded into the database; initial entry by research personnel will be left unverified and only after a second person has completed this entry will the form become complete and verified. A statement reflecting the results of the ongoing data review will be incorporated into the Annual Report for the Independent Monitor.

ii. Frequency of Review

The frequency of data review for this study differs according to the type of data and can be summarized in the following Table:

Frequency of Review TABLE

Data type	Frequency of review	Reviewer
Subject accrual (including compliance with protocol enrollment criteria)	Quarterly	PI, Independent Monitor
Status of all enrolled subjects, as of date of reporting	Quarterly	PI, Independent Monitor
Adherence data regarding study visits and intervention	Quarterly	PI, Independent Monitor
AEs and rates (including out-of-range lab values)	Quarterly	PI, Independent Monitor
SAEs	Per occurrence	PI, Independent Monitor, NIH/NCCIH

H) Subject Accrual and Compliance

iii. Measurement and Reporting of Subject Accrual, Compliance with Inclusion/Exclusion Criteria*:*

Review of the rate of subject accrual and compliance with inclusion/exclusion criteria will occur monthly during the recruitment phase and then every 3 months to ensure that a sufficient number of participants are being enrolled and that they meet eligibility criteria and the targeted ethnic diversity goals outlined in the grant proposal (Targeted/Planned Enrollment Table).

iv. Measurement and Reporting of Participant Adherence to Treatment Protocol

Data on adherence to the treatment protocol will be collected for individual subjects at each visit and reviewed quarterly by the PI, the study coordinator, and the safety officer. Adherence of participants will be evaluated by performing pill counts and by monitoring the appropriate vital signs at each visit. If adherence falls below the rate

of 75%, which might inhibit the ability of the study to test its primary hypotheses, the safety officer will suggest a conference call for study investigators to discuss methods for improving adherence.

I) Justification of Sample Size

We examine the differences in change in pain for placebo responders versus non-responders and the interaction between active treatment and response type. We can estimate statistical power based on the Cohen's d effect sizes for differences in pain with 6-week placebo treatment. For responders, based on our preliminary results, we anticipate a mean decrease of 3 units on a 0-10 scales with an estimated SD of 15, which results in an effect size estimate of 2.0. In non-responders the mean decrease in pain is negligible and we do not expect to have enough power to detect this. Power analyses in G*Power 3.1.3 indicated that we will have ample power. Even with a conservative estimated effect size of d = 1.0, power would be 80% for a sample size of n = 17 per group which would allow to also detect the interaction effects. In addition, it ensures adequate sample sizes even assuming some attrition in each group. For brain imaging contrasts, fMRI results show that 20 per group should be adequate given the preliminary results and earlier studies. For DTI and T1 studies our earlier studies indicate that 25/group for within subject contrasts is adequate but may be just at the limit for whole-brain contrasts for detecting between-group differences.

Phase 1 results are consistent with above power calculations. They also show that a number of predictors were only borderline significant. Thus, increasing the number of treatment arm subjects by an additional 40 patients would provide opportunity to detect smaller effects and to test for gender dependence of placebo response.

J) Stopping Rules

This study will be stopped prior to its completion if: (1) the intervention is associated with adverse effects that call into question the safety of the intervention; (2) difficulty in study recruitment or retention will significantly impact the ability to evaluate the study endpoints; (3) any new information becomes available during the trial that necessitates stopping the trial; or (4) other situations occur that might warrant stopping the trial.

K) Designation of an Independent Monitor

The Independent Monitor for this study is Dr. James (Jim) W. Atchison. Dr. Atchison is not associated with this research project and thus works independently of the PI, Dr. Apkarian. Since Norm is leaving, we need a new person to do this for us.

Dr. Atchison is not a part of the key personnel involved in this grant, and is qualified to review the patient safety data generated by this study because of his/her unique expertise in the area of chronic pain. Dr. Atchison's CV is included at the end of this DSMP.

L) Safety Review Plan

Study progress and safety will be reviewed quarterly (and more frequently if needed). Progress reports, including patient recruitment, retention/attrition, and AEs, will be provided to the Independent Monitor following each of the monthly reviews. An Annual Report will be compiled and will include a list and summary of AEs. In addition, the Annual Report will address (1)

whether AE rates are consistent with pre-study assumptions; (2) reason for dropouts from the study; (3) whether all participants met entry criteria; (4) whether continuation of the study is justified on the basis that additional data are needed to accomplish the stated aims of the study; and (5) conditions whereby the study might be terminated prematurely. The Annual Report will be sent to the Independent Monitor and will be forwarded to the IRB and NCCIH ,FDA, and sponsoring industry collaborator. The IRB and other applicable recipients will review progress of this study on an annual basis.

M) Study Report Outline for the Independent Monitor (Interim or Annual Reports)

The study team will generate Study Reports for the Independent Monitor and will provide information on the following study parameters: Progress reports, including patient recruitment, retention/attrition, and AEs

Study Report tables will be generated only from aggregate (not by group assignment) baseline and aggregate safety data for the study population. A separate Closed Safety Report, with masked group baseline and safety data, will be generated for the Independent Monitor(s) by a designated unmasked member of the team but will not be reviewed by the study team.

N) Informed Consent

Written informed consent will be obtained from each subject at entry into the study. Informed consent is obtained by the following process:

1. The subject (if applicable, parent/guardian) will be asked to review the study consent form.

2. The PI or Co-Investigator (Co-I), or study coordinator will meet with the subject to review the form, to confirm the subject's understanding of the study, and to answer any questions the subject might have.

3. Once the subject demonstrates understanding of the study and agrees to participate in the study, the consent will be signed in the presence of the research coordinator or PI (or Co-I) and a witness.

O) Reporting Changes in Study Status

During the funding of this study, any action by the FDA (if applicable), an IRB, or one of the study investigators that results in a temporary or permanent suspension of the study will be reported to the NCCIH Program Official within 1 business day of notification.

Data and Safety Monitoring Plan

Appendix A

The tables below are EXAMPLE TABLES that can be used or modified to report study progress and patient safety data to oversight groups including the IRB, Independent Monitor(s), NCCIH, and the FDA.

Table 1. Enrollment by Month of Study

Month	# Expected	# Screened	# Enrolled or Randomized	# Withdrawn	# Actual (# Enrolled - # Withdrawn)	# Cumulative (Sum of # Actual by Month)
2	6	4	3	0	3	3
4	8	6	5	1	4	7

*Enrollment can also be displayed graphically in a Figure, with cumulative subject accrual plotted over time.

Table 2. Demographics

Characteristics	N	N%
Gender		
Female		
Male		
Ethnicity		
Hispanic or Latino		
Not Hispanic or Latino		
Unknown		
Age		
Mean (SE)		
Median (min, max)		
Race		
AIAN		
Asian		
Nat Hawaiian/Other Pac Islander		
Black or African American		
White		
Other		
More than one race		
Unknown		

Table 3. Subject Status

Status:
A = Active
C = Completed
W = Withdrew
L = Lost to followup

% Compliance to Intervention:
(# tablets taken/total # per protocol)*100
or
(# classes taken/total # of sessions should have attended per protocol)*100

Pt Identifier	Date Enrolled	Date Completed Study	Study Status	Reason for Withdrawal	% Adherence to Intervention	Intervention Duration (Weeks)
Subj001	08/02/2010	N/A	A			
Subj002	07/26/2010	9/20/2010	C		87%	8 weeks
Subj003	08/04/2010	N/A	W	Injury unrelated to intervention		

Table 4. Adverse Events

Pt Identifier	AE Onset	AE End	AE Code (MedRA, CTCAE)	Severity	SAE? (Y/N)	Related-ness	Action Taken	Outcome	Comments
Subj001	08/02/2010			1		2	1	4	Subj felt Achilles tendon pain during yoga class; history of tendonitis; will not attend class next week
Subj002	07/26/2010			2		2	1	1	
Subj003	08/04/2010			3		0	4	4	Subj broke leg while skiing; withdrew from study

Severity of AE:
1 = Mild
2 = Moderate
3 = Severe
4 = Life threatening or disabling

Relatedness to Intervention:
0 = Definitely unrelated
1 = Unlikely
2 = Possibly related
3 = Probably related
4 = Definitely related

Action Taken:
0 = None
1 = Dose modification

Outcome:
1 = Resolved

2 = Medical intervention (specify in comments)
3 = Hospitalization
4 = Intervention discontinued
5 = Other
2 = Recovered with minor sequelae
3 = Recovered with major sequelae
4 = Continuing treatment
5 = Condition worsening
6 = Patient death**

**Provide further details regarding all reported serious AEs and deaths in the SAE and Subject Deaths tables listed at the end of this section.

Table 5. Frequency of Specific Symptoms

Symptoms	AE Code (MedRA, CTCAE)	N%
Fatigue		
Malaise		
Nausea		
Dizziness		
Muscle Aches		

Table 6. Out-of-Range Laboratory Values

Pt ID	Visit #	HCT	WBC	PLT	Protein	Urine RBC	Creatinine	ALT	AST	Cholesterol	Amylase	BUN	CPK	Related to Intervention
Subj001														
Subj002														
Subj003														

*If the study is collecting data on patient-reported outcomes or other assessments, which should be regularly assessed with safety data during the study, a similar table listing out-of-range values or scores can be generated for the report.

Table 7. Serious Adve9rse Events

Pt Identifier	Age	Treatment Date	SAE	SAE Date	Related to Intervention	Description of Actions and Outcomes (e.g., hospitalization, withdrawn from study)
Subj001						
Subj002						
Subj003						

Table 8. Subject Deaths

Pt Identifier	DOB	Date Enrolled	Treatment Date	Cause of Death	Date of Death	Comments
Subj001		08/02/2010				
Subj002		07/26/2010				
Subj003		08/04/2010				

Table 9. Procedural Events

Visits	1	Interim	2	Interim	3	4	5	6
Informed Consent	X							
Medical History	X							
Concomitant Mediactions	X		X		X	X	X	X
Physical Exam	X							
Vitals	X				X			X
Demographics	X							
Adverse Assessment	X		X		X	X	X	X
Phone app usage	X	X	X	X	X	X	X	X
Pain Rating Stability/Elgibility		X						
Stratification (1 week)				X				
MRI Screening and Collection			X				X	
Study Agent Dispension					X	X		
Drug Compliance						X	X	
PHH	X							
Biological Speciman Collection	X							
Protocol Deviations (if app)	X		X		X	X	X	X
eNOTIS	X							
Study Completion								X
NRS	X		X		X	X	X	X
MPQ	X		X		X	X	X	X
PDt	X		X		X	X	X	X
PIC	X		X		X	X	X	X
ODI	X		X		X	X	X	X
BDI	X				X	X	X	X
PCS	X							
ERQ	X							
MAIA	X							
LAQ	X							
TSS						X	X	
MHLC-C								X
MISS								X
HCAHQ								X

Curriculum Vitae

James W. Atchison, D.O.
Medical Director
Center for Pain Management
Rehabilitation Institute of Chicago
980 N. Michigan Ave., Suite 800
Chicago, IL 60611
312-238-7825/312-238-7881 Fax

MEDICAL LICENSURE

Illinois #036131304, Sept 2012
Florida #OS 7098, Sept 1995
Ohio #4622, Sept 1988 - Inactive

DIPLOMATE

National Board of Osteopathic Medical Examiners, #14972, July 1988

SPECIALITY BOARDS

American Board of Physical Medicine and Rehabilitation, #3373, May 1992
American Board of Physical Medicine and Rehabilitation, Pain Medicine, #360, Sept 2003
American Board of Electrodiagnostic Medicine, #1685, April 1993

HIGH SCHOOL/UNDERGRADUATE EDUCATION

1969 – 1973 Carrollton High School; Carrollton, OH; Degree: Diploma
1973 – 1977 Wittenberg University; Springfield, OH; Degree: Bachelor of Arts in Biology
- Phi Gamma Delta – Men's Social Fraternity
- Men's Intercollegiate Basketball, 1973-74, 1974-75
- Student Assistant Coach, Men's Intercollegiate Basketball, 1975-76, 1976-77. (NCAA Division III National Champions, 1977; National Runners-up, 1976)

HIGH SCHOOL TEACHING

1977 – 1978 Greenon High School; Enon, OH
- Instructor: Physics, Introductory Science
- Coach: Varsity Assistant Football, Basketball and Baseball

1978 – 1980 Triad High School; North Lewisburg, OH
- Instructor: Physics, Chemistry, General Science
- Coach: Head Men's Basketball, Head Men's and Women's Track, Varsity Assistant Football

1980 – 1983 Springboro High School; Springboro, OH
- Instructor: Introductory Chemistry and Physics, Biology
- Coach: Head Men's and Women's Cross Country, Head Women's Track, Assistant Men's Basketball

14.0 MEDICAL SCHOOL

1983 – 1987 Ohio University College of Osteopathic Medicine (OUCOM); Athens, OH; Degree: Doctor of Osteopathy

- President OUCOM Sports Medicine Club, 1984 – 1985
- Social Chairman OUCOM Student council, 1984 – 1985

INTERNSHIP

1987 – 1988 Rotating; Cuyahoga Falls General Hospital; Cuyahoga Falls, OH

RESIDENCY

1988 – 1991 Physical Medicine and Rehabilitation; The Ohio State University; Columbus
- Resident Liaison to the Resident Physician Council of the American Academy of Physical Medicine and Rehabilitation (AAPM&R), 1990, 1991
- AAPM&R Resident Physician Council Membership Committee, 1991

ACADEMIC APPOINTMENTS

8/1/91 - 1996 Assistant Professor; University of Kentucky, College of Medicine, Department of Physical Medicine and Rehabilitation; Lexington, KY

01/96 – 2001 Associate Professor; University of Florida, College of Medicine, Departments of Orthopaedics and Rehabilitation and Neurological Surgery; Gainesville, FL

01/02 – 06/05 Clinical Associate Professor University of Florida, College of Medicine, Departments of Orthopaedics and Rehabilitation and Neurological Surgery

07/05- 09/12 Clinical Professor University of Florida, College of Medicine, Department of Orthopaedics and Rehabilitation, Division of Physical Medicine and Rehabilitation

8/27/12-Present Professor in Physical Medicine and Rehabilitation, Northwestern University, Feinberg School of Medicine

15.0 CLINICAL APPOINTMENTS

08/01/91 – 1996 Cardinal Hill Rehabilitation Hospital, Department of Rehabilitation Medicine, Lexington, KY

08/01/91 – 1996 Chandler Medical Center, University of Kentucky, Department of Physical Medicine and Rehabilitation, Lexington, KY

08/01/96 – 1996 Veterans Administration Hospital, Cooper Drive, Lexington, KY

0 8/01/91 – 1996 Shriner's Hospital, 1900 Richmond Road, Lexington, KY

08/01/94 – 1996 Highlands Regional Medical Center, Prestonsburg, KY

01/02/96 – 8/27/12 Shands Medical Center at University of Florida, Gainesville, FL

02/01/97 – 8/27/12 Shands Rehabilitation Hospital, Gainesville, FL

06/25/97 – 2010 Shands at Alachua General Hospital, Gainesville, FL (Hospital Closed)

8/27/12- Present Rehabilitation Institute of Chicago, Chicago, IL

ADMINISTRATIVE APPOINTMENTS

01/01/96-09/2011 Medical Director; SpineCare Center, Department of Orthopaedics and Rehabilitation, University of Florida, Gainesville, FL

02/01/97-8/27/12 Medical Director; Shands Rehabilitation Hospital, Gainesville, FL

02/01/97-06/30/98 Interim Chief; Division of Physical Medicine and Rehabilitation, Department of Orthopaedic Surgery, University of Florida, Gainesville, FL

07/01/98-09/2011 Chief; Division of Physical Medicine and Rehabilitation, Department of Orthopaedics and Rehabilitation, University of Florida, Gainesville, FL

8/27/12-Present Medical Director, Center for Pain Management, Rehabilitation Institute of Chicago, Chicago, IL

CONSULTING

1989 – 1991 Rehabilitation Service Commission of Ohio, Bureau of Disability Determination; Columbus, OH

1089 – 1991 Ohio Bureau of Workers' Compensation; Columbus, OH

1992 – 1996 University of Kentucky Student Health Services; Lexington, KY

1992 – 1996 University of Kentucky Athletic Department; Lexington, KY

CONSULTING (Continued)

2005 – 2011 Florida C.A.R.E.S.; Gainesville, FL

2009 – 2012 Best Doctors, Inc.; Boston, MA

2014- Present Best Doctors, Inc., Boston, MA

2015- Present INSPE Associates Ltd., Chicago, IL

16.0 REVIEWER

American Journal of Physical Medicine and Rehabilitation

- Article Reviewer: 1991 – 2006, 2012
- Editorial Board; 2001 – 2006

17.0 Archives of Physical Medicine and Rehabilitation

- Article Reviewer: 1996 – 2009

Pain Medicine

- Article Reviewer: 2011 – Present

Association of Academic Physiatrists

- Education Committee
  - White Paper on Fellowships, March 1993
  - "Spinal Biomechanics I and II," September 1997

American Academy of Physical Medicine and Rehabilitation

- Practice Parameters Committee
  - AHCRP Clinical Practice Guidelines for "Acute Low Back Problems in Adults," November 1994
  - American Academy of Orthopedic Surgeons Algorithms for "Hip Pain, Knee Pain, Knee Injury, Wrist Pain, Shoulder Pain, and Low Back Pain," September 1995
- American Academy of Orthopedic Surgeons Algorithms for "Herniated Lumbar Disc, Spinal Stenosis, Low Back Musculoligamentous Injury, Phase I Ankle Injury, Phase II Knee Pain, Hallus Valgus, and Pes Planus," Aug 1996
- "The Fibromyalgia Syndrome: A Consensus Report on Fibromyalgia and Disability," Jul 1997
  - "AAOS Phase I Wrist Pain Guideline" and "AAOS Phase I Ankle Injury Guideline," May 1999

18.0 Journal of Back and Muscloskeletal Rehabilitation

- Editorial Board; 1999 - Present
- Article Reviewer; 1999 - Present

19.0 Foundation for Physical Medicine and Rehabilitation

- ERF Best Research Paper Applications, August 2003

20.0 The Retirement Research Foundation

- Proposal Reviewer, June 1998

21.0 U.S. Dept of Education, Office of Special Education & Rehabilitative Services

- Proposal Reviewer for Brain Injury Model System Sites, August 1998
- Proposal Reviewer for Work Training/Vocational Rehab Programs for the Disabled.

July 2002

- Proposal review for SCI Model Systems Sites, August 2011

iSpine

- Text Reviewer; 2011

21.1 HIGHER EDUCATION TEACHING

Summer 1984 Ohio University College of Osteopathic Medicine. Athens, OH

HIGHER EDUCATION TEACHING (Continued)

- Laboratory Teaching Assistant for Gross Anatomy and Osteopathic Clinical Principles Course for the Summer Studies Program for Disadvantaged Candidates

Summer 1991 University of Kentucky Medical School

08/1991 – 1996 University of Kentucky Department of Rehabilitation Medicine Residents

- Daily Rounds on Stroke Module I and II
- Weekly Grand Rounds
- Biweekly Case Conferences
- Biweekly EMG Case Conferences
- Monthly Journal Club
- Weekly Tuesday Morning Resident Course
- Biweekly Supervision of Outpatient Clinic at VA Medical Center
- Biweekly Supervision of Outpatient Clinics at PM&R Offices

1991 – 1992 University of Kentucky Medical Students: 4 students for 4-week rotation in Medicine

Summer 1992 University of Kentucky Medical School

- Conjoint 831 for 3rd year Medical Students

University of Kentucky Office for Experimental Education Internship

- 1 post-graduate student, 6 hours/week, 8 weeks

1992 – 1993 University of Kentucky Medical Students: 2 students for 4-week rotation in Medicine

Spring 1993 University of Kentucky Medical School

- Introduction to Physical Diagnosis – Medicine 821; weekly group sessions for 2nd year medical students, 4 students

1993 – 1994 University of Kentucky Medical Students

- 3 students for 4-week rotation in Medicine
  - Elective in Physical Medicine and Rehabilitation: 2 students for 4-week rotation

22.0 1993 -1994 University of Kentucky Medical Students (continued)

23.0 - Introduction to Physical Diagnosis – Medicine 821: biweekly group sessions for 2nd year medical students, 4 students

University of Kentucky Department of Biomechanical Engineering

- Graduate student interaction/partial supervision of ongoing research projects, 4 students

Summer 1994 University of Kentucky Medical Students

- Summer research projects: 2 students for 8 weeks
- Medical Student Elective in Physical Medicine and Rehabilitation
  - Visiting medical student from Southeastern College of Osteopathic Medicine

1994 – 1995 University of Kentucky Medical Students: 6 students for 4-week rotation in medicine

- Daily Rounds on Stroke Rehabilitation Module I and II
- Weekly Grand Rounds
- Monthly Student Report on a Rehabilitation topic of Choice

1994 – 1995 University of Kentucky Medical School

- Introduction to Physical Diagnosis – Medicine 821, biweekly group sessions for 2nd year medical students, 4 students

23.1 HIGHER EDUCATION TEACHING (Continued)

- 4th Year Gerontology Clerkship
  - Five times/week clinical/didactic session, 14 students
  - Problem based learning tutor, 8 sessions, 5 students

1994 - 1995 University of Kentucky Department of Biomechanical Engineering

- Graduate student interaction/partial supervision for ongoing research projects, 2 students

1995 University of Kentucky Medical School

- 4th Year Gerontology Clerkship, 5 times/week clinical/didactic sessions, 4 students

University of Kentucky Department of Biomechanical Engineering

- Masters committee for thesis candidate, Liz Knapp

1996 – 2012 University of Florida College of Medicine

- 2nd Year Geriatrics Rotation (1996, 1997)
  - Assistance Technology for Geriatric Rehabilitation. Introduction to Gerontology and Geriatrics

- 3rd Year Geriatrics Rotation (1996 – 2005)
    - Introduction to Rehabilitation Principles – Immobility/ Deconditioning, 10 students, 1 time/month
- Introduction to the Aging Spine – Rehabilitation Treatment Approach to Arthritis, Spinal Stenosis, and Osteoporosis, 10 students, 1 time/month
- 3rd Year Clerkships (1996 – 2005)
    - Clinical Instruction in SpineCare Center
- Department of Orthopaedics and Rehabilitation
- Lectures on Evaluation and Treatment of Low Back Pain and Neck Pain
- Clinical Training of Orthopaedics Spine Fellow in SpineCare Center
- Weekly Spine Conference with Orthopaedics/ Neurosurgery Residents
- Physician Assistant Students
    - Lectures on Evaluation and Treatment of Low Back Pain and Neck Pain
- Rheumatology
    - Rheumatology Spine Fellowship
    - Clinical Instruction in SpineCare Center
- Psychiatry
- Special Topics Seminar, Geriatric Psychiatry Fellowship
    - Lecture on Physical Medicine and Rehabilitation in Geriatrics – Enabling the Elderly

2006 – 2012 University of Florida Medical Students

4th Year Elective in Physical Medicine and Rehabilitation: 2-Week Rotation

4th Year Elective in Musculoskeletal Medicine: 2-Week Rotation

4th Year Geriatric Clerkship: 2-Week Rotation

1996 – 2012 University of Florida College of Nursing

- Clinical Rotations in SpineCare Center for ARNP Students

2012 – Spring

- Nurse Practitioner Practicum for spring 2012 semester at the Shands Rehab Hospital. (288 hours)

1997 – 2001 University of Florida College of Health Professions

HIGHER EDUCATION TEACHING (Continued)

- Department of Clinical and Health Psychology
- Dissertation Committee for John Otis, Ph.D. Candidate

1999 – 2011 University of Florida, Department of Orthopaedics & Rehabilitation

- Spine & Musculoskeletal Medicine Fellowship Director (1999-2011)
    - 1999-2000 Michael Meighen, M.D.
    - 2000-2001 Ephraim K. Brenman, D.O.
    - 2001-2002 Carlos J. Placer, M.D.
    - 2002-2003 Arthur J. Kalman, D.O.
    - 2003-2004 Mara Isser, D.O.

- 2004-2005 Alberto Rivera, M.D.
- 2005-2006 Nandita S. Keole, M.D.
- 2005-2006 Javier A. Placer, M.D.
- 2006-2007 Joseph Ferraro, M.D.
- 2006-2007 Samuel Nortman, M.D.
- 2007-2008 Don Mascarenhas, M.D.
- 2007-2008 Marisol Arcila, M.D.
- 2008-2009 Adam Berliner, D.O.
- 2008-2009 Stanford Williamson, D.O.
- 2009-2010 Robert "Jamie" Spicer, D.O.
- 2010-2011 Maximillian Shokat, D.O.
- 2010-2011 Maureen Noh, M.D.
- 2011-2012 A. Scott Hamilton, M.D.
- 2011-2012 Quang T. (Wayne) Nguyen, M.D.

1999 – 2012 University of Florida, College of Medicine
- Geriatric Medicine Fellow Rotations

2002 – 2004 University of Florida College of Health Professions
- Department of Health Services Administration, Brooks Center for Rehabilitation Studies
- Physician Collaborator for Steven George, PhD, PT

2012 – 2012 University of Florida, College of Medicine
- Stroke Fellowship/Neurorehabiltation Inpatient Care Rotation

March 2012 University of Florida, College of Medicine
- AHMA Back Pain Seminar – Medical Student

University of Florida/North Florida/South Georgia Veterans Health System
- Geriatric Research Education & Clinical Centers – Geriatric Fellowship Noon Conference – Principles of Pain Management

24.0

25.0 TEACHING AT THE NATIONAL LEVEL

1999 - Present
- "Principles of Manual Medicine." American Academy of Physical Medicine and Rehabilitation Annual Meetings.

May 2004
- "*Emerging concepts in the diagnosis and treatment of pain. An intensive and comprehensive review*." American Academy of Physical Medicine and Rehabilitation. New Orleans, LA (Program Committee Co-Chair)

May 2005
- "*Emerging concepts in the diagnosis and treatment of pain. An intensive and comprehensive review."* American Academy of Physical Medicine and Rehabilitation.

26.0 TEACHING AT THE NATIONAL LEVEL (Continued)

New Orleans, LA (Program Committee Co-Chair)

June 2005 - "*Emerging concepts in the diagnosis and treatment of pain. An intensive and comprehensive review."* (Program Committee Co-Chair) American Academy of Physical Medicine and Rehabilitation. San Francisco, CA.

27.0 RESIDENT LECTURES

Aug 1991 - Bladder Anatomy and Dysfunction (CHRH)
- Upper and Lower Limb – Neuromusculoskeletal Examination and Clinical/Anatomic Correlates (CHRH)

Sep 1991 - Basics of Electromyography/Nerve conduction Studies (CHRH)
- Radial Nerve Studies (CHRH)
- Prevention and Treatment of Pressure Ulcers (CHRH)

Oct 1991 - Aphasia – diagnosis and classification (CHRH)
- Upper Limb – Neuromusculoskeletal Examination and Clinical/Anatomic Correlates (CRRH)
- Diagnosis and Treatment of Reflex Sympathetic Dystrophy (CHRH)
- Median Motor and Sensory Nerve Conduction Studies (CHRH)
- Knee Anatomy and Examination (VA)
- Knee Rehabilitation and Bracing (VA)

Nov 1991 - Bladder Anatomy and Dysfunction (CHRH)
- Lower Limb – Neuromusculoskeletal Examination and Clinical/Anatomic Correlates (CHRH)
- Neuroradiology – Central Nervous System Course (ALL)
- Use of Nerve and Motor Point Blocks (CHRH)
- Facial EMG and Nerve conduction Studies (CHRH)

Dec 1991 - Diagnosis and Treatment of Parkinson's Disease (CHRH)
- Ulnar Motor and Sensory Nerve Conduction Studies (CHRH)
- Upper and Lower Limb – Neuromusculoskeletal Examination and Clinical/anatomic Correlates (VA)

Jan 1992 - Biomechanics of Normal Human Locomotion (VA)
- Therapeutic Exercise and Strength Training (VA)
- Treatment of Upper Motor Neuron Spasticity (CHRH)
- Prophylaxis, Diagnosis, and Treatment of Deep Venous Thrombosis (CHRH)
- Use of Antidepressants and Antianxiolytics Following Stroke (CHRH)
- Multiple Sclerosis and Amyotrophic Lateral Sclerosis for CNS Course (ALL)

Feb 1992 - Prophylaxis of Seizures Following Stroke (CHRH)
- Bladder anatomy and Dysfunction (CHRH)
- Differential Diagnosis of Low Back Pain (VA)
- Use of Cervical Traction (VA)

Mar 1992 - Pulmonary Rehabilitation (VA)
- Diagnosis and Treatment of Spinal Stenosis (VA)
- Lower Limb Nerve Conduction Studies
- Differentiation of Upper Motor Neuron vs Lower Motor Neuron Firing Pattern by EMG (CHRH)

- Use of F Waves and H Reflexes (CHRH)

RESIDENT LECTURES (Continued)

Apr 1992
- Diagnosis and Treatment of Fibromyalgia (VA)
- Examination and Biomechanics of Shoulder Function (VA)

May 1992
- Myasthenia Gravis, Myastenic Syndrome, and Repetitive Stimulation (VA)
- Treatment of Plantar Fascitis (VA)
- Aphasia – Diagnosis and Classification (CHRH)
- Use of Antidepressants and Antianxiolytics Following Stroke (CHRH)
- Prophylaxis of Seizures Following Stroke (CHRH)

Jun 1992
- Ankylosisng Spondylitis and the Arthridites (VA)
- Diagnosis and Treatment of Spinal Stenosis (VA)
- Analysis of Normal and Pathologic Gait (CHRH)
- Use of Manual Medicine (CHRH)

Jul 1992
- Bladder Anatomy and Dysfunction (CHRH)
- Prophylaxis, Diagnosis, and Treatment of Deep Venous Thrombosis (CHRH)
- Asphasia – Diagnosis and Classification (CHRH)
- Prophylaxis of Seizures Following Stroke (CHRH)
- Lower Limb Nerve Conduction Studies (VA)
- Introduction of Electrodiagnostic Instrumentation (ALL)
- Introduction to Electrodiagnostic Needle Examination (ALL)

Jul 1992
- Manual Medicine Mini-Course Within Musculoskeletal Course (ALL)
- Introduction to Anatomy and Biomechanics of the Spine
- Evaluation and Treatment of the Cervical Spine
- Evaluation and Treatment of Ribs and the Thoracic Spine
- Evaluation and Treatment of Lumbar Spine, Pelvis, and Sacrum

Aug 1992
- Motor Nerve Conduction Studies (ALL)
- Sensory Nerve Conduction Studies (ALL)
- Electrodiagnostic Evaluation of Tarsal Tunnel Syndrome (VA)
- Diagnosis and Treatment of Lumbar Stenosis (VA)
- Classification of Impairment, Handicap, and Disability (Conjoint 831)

Sep 1992
- Motor Unit Analysis, Part I (ALL)
- Basic Carpal Tunnel Analysis/Screen (ALL)
- Introduction to F Waves/H Reflexes (ALL)

Oct 1992
- Motor Unit Analysis, Part II (ALL)
- Electrodiagnostic Analysis of the Fascial Nerve (ALL)
- How to Evaluate a Patient With Low Back Pain (CHRH-AIs)
- Medial Calcaneal Nerve Conduction Studies (VA)
- Lateral Femoral Cutaneous Nerve Studies (VA)
- Bladder Anatomy and Dysfunction (CHRH)
- Prophylaxis, Diagnosis, and Treatment of Deep Venous Thrombosis (CHRH)

Nov 1992
- Averaging/F Wave Techniques (VA)
- Lower Limb Nerve Conduction Screen (ALL)
- Use of Antidepressants and Antianxiolytics Following Stroke (CHRH)

- Prophylaxis of Seizures Following Stroke (CHRH)

RESIDENT LECTURES (Continued)

Dec 1992
- Principles in Orthotic Use and Bracing Following CVA (CHRH)
- Saphenous Nerve Studies (VA)
- Controversies in the Use of Steroids Following CVA (CHRH)
- Superficial Peroneal Nerve Studies (VA)

Jan 1993
- Electrodiagnosis of Peroneal N. Palsy (VA)
- Lateral Antebrachial Cutaneous Nerve Studies (CHRH)
- How to Evaluate a Patient With Low Back Pain (CHRH-AIs)

Feb 1993
- Anterior Interosseous Syndrome (VA)
- Diagnosis of Hereditary Sensory Motor Neuropathies (VA)
- Evaluation of the Hemiplegic Shoulder (CHRH)
- Diagnosis and Classification of Peripheral Neuropathy (VA)
- How to Evaluate a Patient With Low Back Pain (CHRH-AIs)
- Use of Antispasticity Medicine Following Stroke (CHRH)

Mar 1993
- Analysis of Normal and Pathologic Gait (CHRH)
- Alternative Ulnar Nerve Conduction Studies (VA)
- Controversies in the Use of Steroids Following CVA (CHRH)
- Techniques in Repetitive Stimulation (VA)
- Principles in Orthotic Use and Bracing Following CVA (CHRH)

Apr 1993
- Motor Unit Analysis, Part I (CHRH)
- Comparison of Lower Limb Sensory Nerve Studies (VA)
- Evaluation of Spontaneous EMG Potentials (CHRH)

May 1993
- Motor Unit Analysis, Part II (ALL)
- How to Evaluate a Patient With Low Back Pain (CHRH-AIs)
- Evaluation and Treatment of the Hemiplegic Shoulder (CHRH)

Jun 1993
- Analysis of Normal and Pathologic Gait (CHRH)
- Controversies in the Use of Steroids Following CVA (CHRH)
- Use of Antispasticity Medicine Following Stroke (CHRH)

Jul 1993
- Principles in Orthotic Use and Bracing Following CVA (CHRH)
- Prophylaxis, Diagnosis, and Treatment of Deep Venous Thrombosis (CHRH)
- Analysis of Normal and Pathologic Gait (CHRH)
- Principles of Geriatric Rehabilitation (ALL)

Aug 1993
- Introduction to Electrodiagnostic Instrumentation (ALL)
- Introduction to EMG Need Examination (ALL)

Sep 1993
- Motor Nerve Conduction Studies (ALL)
- Sensory Nerve Conduction Studies (ALL)
- How to Evaluate a Patient With Low Back Pain (CHRH-AIs)
- Motor Unit Analysis, Part I (ALL)

Oct 1993
- How to Evaluate a Patient With Low Back Pain (CHRH-AIs)
- Basic Carpal Tunnel Analysis/Screen (ALL)

- Introduction to F Waves/H Reflexes (ALL)

Nov 1993 - Motor Unit Analysis, Part II (ALL)

- Evaluation and Treatment of Shoulder Pain/Dysfunction (UK)
- How to Evaluate a Patient With Low Back Pain (CHRH-AIs)
- Neuroradiology for CNS Course (ALL)

RESIDENT LECTURES (Continued)

Dec 1993 - Basic Lower Limb Nerve Conduction Screen (ALL)

Jan 1994 - How to Evaluate a Patient With Low Back Pain (CHRH-AIs)

- Electrodiagnostic Analysis of the Facial Nerve (ALL)
- Bladder Anatomy and Dysfunction (CHRH)
- EMG Waveform Analysis, Part I (ALL)
- Principles in Orthotic Use and Bracing Following CVA (CHRH)

Feb 1994 - Prophylaxis, Diagnosis, and Treatment of Deep Venous Thrombosis (CHRH)

- Prophylaxis of Recurrent CVA (CHRH)
- Evaluation and Treatment of the Hemiplegic Shoulder (CHRH)
- EMG Waveform Analysis, Part II (ALL)
- Ulnar Motor and Sensory Nerve Conduction Studies (ALL)

Mar 1994 - Multiple Sclerosis and Amyotrophic Lateral Sclerosis for CNS Course (ALL)

- How to Evaluate a Patient With Low Back Pain (CHRH-AIs)
- Needle Stimulation and Recording for Difficult Nerve Conduction Studies (ALL)
- Repetitive Stimulation Techniques (ALL)

Apr 1994 - Unusual Nerve Conduction Studies (ALL)

- How to Evaluate a Patient With Low Back Pain (CHRH-AIs)
- EMG Needle Exam – Upper Limb Anatomy and Screening Exam (ALL)
- Evaluation and Treatment of the Hemiplegic Shoulder (CHRH)

May 1994 - Controversies in the Use of Steroids Following CVA (CHRH)

- Use of Antispasticity Medicine Following Stroke (CHRH)
- EMG Needle Exam – Lower Limb Anatomy and Screening Exam (ALL)
- Principles in Orthotic Use and Bracing Following CVA (CHRH)
- Review of EMG/NCS for Carpal Tunnel Analysis (ALL)

Jun 1994 - Analysis of Normal and Pathologic Gait (CHRH)

- Review of Difficult EMG/NCS Cases (ALL)

Jul 1994 - Manual Medicine Mini-Course Within Musculoskeletal Course (ALL)

- Evaluation and Treatment of the Cervical Spine (ALL)
- Evaluation and Treatment of the Lumbar Spine (ALL)
- Evaluation and Treatment of Pelvis and Sacrum (ALL)

Aug 1994 - Introduction to Electrodiagnostic Instrumentation (ALL)

- How to Evaluate a Patient With Low Back Pain (CHRH-AIs)
- Analysis of Normal and Pathologic Gait (CHRH-AIs)
- Evaluation and Treatment of the Hemiplegic Shoulder (CHRH-AIs)

- Prophylaxis, Diagnosis, and Treatment of Deep Venous Thrombosis (CHRH-AIs)
- Principles in Orthotic Use and Bracing Following CVA (CHRH-AIs)
- Bladder Anatomy and Dysfunction (CHRH-AIs)
- Use of Antidepressant and Antianxiolytics Following Stroke (CHRH-AIs)

RESIDENT LECTURES (Continued)

Sep 1994
- Evaluation and Treatment of the Hemiplegic Shoulder (CHRH/Ger)
- Analysis of Normal and Pathologic Gait (CHRH/Ger)
- Principles in Orthotic Use and Bracing Following CVA (CHRH/Ger)
- Alternative Treatments for Pain in the Elderly (CHRH/Ger)
- Bladder Anatomy and Dysfunction (CHRH/Ger)
- Use of Unconventional Medication in Geriatric Rehabilitation (CHRH/Ger)
- Principles of Diagnosis and Treatment of Reflex Sympathetic Dystrophy (CHRH/Ger)
- Use of Antidepressants and Antianxiolytics Following Stroke (CHRH/Ger)
- Prophylaxis of Seizures after Stroke (CHR/Ger)
- Medications to be Avoided in the Elderly (CHRH/Ger)

Oct 1994
- How to Evaluate a Patient With Low Back Pain (CHRH-AIs/Ger)
- Analysis of Normal and Pathologic Gait (CHRH/AI/Ger)
- Prophylaxis, Diagnosis, and Treatment of Deep Venous Thrombosis (CHRH/AI/Ger)
- Use of Antispasticity Medicine Following Stroke (CHRH/AI/Ger)
- Use of Unconventional Medication in Geriatric Rehabilitation (CHRH/AI/Ger)
- Use of Antidepressants and Antianxiolytics Following Stroke (CHRH/AI/Ger)
- Medications to be Avoided in the Elderly (CHRH/AI/Ger)
- Evaluation and Treatment of the Hemiplegic Shoulder (CHRH/AI/Ger)
- Alternative Treatments for Pain in the Elderly (CHRH/AI/Ger)

Nov 1994
- Introduction to EMG Needle Examination (ALL)
- How to Evaluate a Patient with Low Back Pain (CHRH-AIs/Ger)

Dec 1994
- Motor Unit Analysis, Part I (ALL)

Jan 1995
- EMG Needle Exam – Upper Limb Anatomy and Screening Exam (ALL)
- Evaluation and Treatment of the Hemiplegic Shoulder (CHRH/Ger)
- Analysis of Normal and Pathologic Gait (CHRH/Ger)
- Bladder Anatomy and Dysfunction (CHRH/Ger)
- Medications to be Avoided in the Elderly (CHRH/Ger)

Feb 1995
- Physiology of Exercise (ALL)
- Needle Stimulation Techniques (ALL)
- Cancer Rehabilitation (ALL)
- EMG Needle Exam – Lower Limb Anatomy and Screening Exam (ALL)

- Use of Unconventional Medication in Geriatric Rehabilitation (CHRH/Ger)
- Principles of Diagnosis and Treatment of Reflex Sympathetic Dystrophy (CHRH/Ger)
- Use of Antidepressants and Antianxiolytics Following Stroke (CHRH/Ger)
- Medications to be Avoided in the Elderly (CHRH/Ger)

Mar 1995
- EMG Waveform Analysis: Video Review (ALL)
- How to Evaluate a Patient With Low Back Pain (CHRH/AI/Ger)
- The Essentials of Electrodiagnostic Instrumentation (ALL)
- Analysis of Normal and Pathological Gait (CHRH/Ger)
- Principles in Orthotic Use and Bracing Following CVA (CHRH/Ger)

RESIDENT LECTURES (Continued)

- Bladder Anatomy and Dysfunction (CHRH/Ger)
- Use of Antidepressants and Antianxiolytics Following Stroke (CHRH/Ger)
- Medications to be Avoided in the Elderly (CHRH/Ger)

Apr 1995
- The Basics of Electrodiagnostic Examination and Interpretation (ALL)
- Repetitive Stimulation Techniques (ALL)
- Unusual Stimulation Techniques (ALL)
- Evaluation and Treatment of the Hemiplegic Shoulder (CHRH/Ger)
- Medications to be Avoided in the Elderly (CHRH/Ger)
- Use of Unconventional Medication in Geriatric Rehabilitation (CHRH/Ger)
- Principles of Diagnosis and Treatment of Reflex Sympathetic Dystrophy (CHRH/Ger)

May 1995
- Electrodiagnostic Evaluation of Motor Neuron Disease (ALL)
- Principles of Diagnosis and Treatment of Reflex Sympathetic Dystrophy (CHRH)
- Principles in Orthotic Use and Bracing Following CVA (CHRH)
- Bladder Anatomy and Dysfunction (CHRH)

June 1995
- Evaluation and Treatment of the Hemiplegic Shoulder (CHRH)
- Use of Unconventional Medication in Geriatric Rehabilitation (CHRH)
- Analysis of Normal and Pathologic Gait (CHRH)

Jul 1995
- Department of PM&F Orientation for PGY-IS
- Department of PM&R Orientation for PGY-II
- Bladder Anatomy and Dysfunction (CHRH/Ger)
- Analysis of Normal and Pathologic Gait (CHRH)

Aug 1995
- Introduction to Electrodiagnostic Instrumentation (ALL)
- Anatomy and Kinesiology of the Lower Leg (ALL)
- Sensory Nerve Conduction Studies (ALL)

Sept 1995
- Anatomy and Kinesiology of the Cervical Spine (ALL)

Oct 1995
- Motor Unit Analysis, Part I (ALL)

Nov 1995
- Rehabilitation of the Acute Stroke Patient (ALL)

Dec 1995
- Needle Stimulation and Pin Pick-up Techniques (ALL)

Sep 2011
- Spine – Spinal Cord Injury (OSMI – Ortho Morning Conference)

Jan 2014
- Overview of Opioid Management- PGY-2 (RIC)
- Rational Polypharmacy- PGY-2 (RIC)

March 2014 - Opioids II -advanced series – (RIC)
August 2014 - Intro to Pain Management- PGY-2 (RIC)
Oct 2014 - Opioids I- (RIC)
- Opioids II- (RIC)
Dec 2014 - Functional Measures- (RIC)
Feb 2015 - WC/ SSI/ Disability/ Impairment- (RIC)
March 2015 - Outcomes for CRPM/WC/CRPS- (RIC)
April 2015 - Opioids I- (RIC)
- Opioids II- (RIC)
May 2015 - Worker's Comp- PGY-3 and PGY-4 (RIC)
- Interdisciplinary Approach to Chronic Pain- PGY-2 (RIC)
- FCE and Impairment Ratings- PGY- 3 and PGY-4 (RIC)
- WC/ IME's

28.0 ADVISING ACTIVITY

1991 – 1992 - University of Kentucky – Medical Students (1)
- University of Kentucky , Department of Rehabilitation Medicine – Residents for Research Requirements (3)
Summer 1992 - University of Kentucky, Office for Experimental Education Internship (1)

1992 – 1993 - University of Kentucky, Department of Rehabilitation Medicine – Residents for Research Requirements (5)
- University of Kentucky – Medical Students (4)
1993 – 1994 - University of Kentucky, Department of Rehabilitation Medicine – Residents for Research Requirements (4)
1994 – 1995 - University of Kentucky, Department of Physical Medicine and Rehabilitation – Residents for Research Requirements (5)
- University of Kentucky, College of Nursing. Doctoral Candidate: Deborah Reed
- University of Kentucky, Department of Biomechanics. Master's Candidate: Liz Knapp
1995 – 1996 - University of Kentucky, Department of Biomechanics. Master's Candidate: Liz Knapp
1996 – 2001 - University of Florida, Department of Clinical & Health Psychology. Ph.D. Candidate: John Otis
2002 – 2003 - University of Florida, College of Medicine. 4th Year Medical Student: Kevin Vincent, Ph.D.
- University of Florida, College of Medicine. 4th Year Medical Student: Marisol E. Arcila.

29.0

2003 - 2004 - University of Florida, College of Medicine. 4th Year Medical Student

James Lopez
- University of Florida, College of Medicine. 4th Year Medical Student

David James Kennedy

2004 – 2005 University of Florida, College of Medicine. 4th Year Medical Student Sheryce Andrews

2006 – 2007 University of Florida College of Medicine. 4th Year Medical Student Matthew T. Smith

University of Florida College of Medicine. 4th Year Medical Student Wesley Chay

University of Florida College of Medicine. 4th Year Medical Student

Timi Tuamokumo

2008 – 2009 University of Florida College of Medicine. 4th Year Medical Student Jeffrey Faricielli

30.0

31.0 ADMINISTRATIVE ACTIVITY

1991 – 1996 **University of Kentucky, College of Medicine**

- Search Committee for Chair, Department of Physical Medicine & Rehabilitation; 1995
- Clinical Sciences Self-Study Committee; 1995
- Graduate Medical Education Committee; 1995
- Internal Residency Review Committee for Occupational/Preventive Medicine; 1995
- Research Committee; 1995

ADMINISTRATIVE ACTIVITY (Continued)

1991 – 1996 **University of Kentucky, Dept of Physical Medicine & Rehabilitation**

- Research Committee
- Resident Recruitment Committee
- Organization of Resident Recruitment; 1994–1995
- Education Committee
- Development of Course: "Introduction to Rehabilitation Medicine for Medical Students"
- Development of Dept of Rehabilitation Medicine Evaluation Forms
- Student Evaluation of Faculty Lectures – "Introduction to Rehab Medicine"
- Student Evaluation of Departmental Rotations
- Resident/Faculty Evaluation of "Chief Rounds" Lectures
- Development of Educational Syllabus for Stroke Rotation
- Co-Development of Educational Syllabus for General Rehabilitation Rotation
- Co-Development of the Required Teaching Guidelines for the VA Residents
- Development of PM&R Student Health Clinic – ½ day/week (Jan 1992)
- Co-Course Director: Residents Thursday Course – "Manual Medicine" (with Musculoskeletal Course, Jul 1992, Jul 1994)
- Development of PM&R/Manual Medicine Consultation Services for Department of Athletics (Aug 1992)

- Course Director: "Introduction to Electrodiagnosis for Resident" (Jul 1992 – Dec 1992, Aug 1993 – Jun 1994, Aug 1994 – Jun 1995)
- Co-Course Director: Residents Thursday Course – "Prosthetics and Orthotics " (Spring 1992)
- Development of Yearly Evaluation for Resident Competency/Skills in EMG/NCS
- Course Director for Tuesday Morning Residents Lecture Series (Aug 1994-1996)
- Course Director: Residents Thursday Course "Electrodiagnosis (Spring 1995)

1993 – 1994
- Assistant Residency Program Director
- Departmental Coordinator of Medical Student Rotations
- Research Committee, Chair

1994 – 1995
- Departmental Coordinator of 4th Year Gerontology Clerkship, MD 841
- Departmental Coordinator of Medical Student Rotations
- Research Committee, Chair
- Preparation of Document for Residency Review Committee – 1994
- Course Director for CME Course "Clinical Osteopathic Manual Medicine: An Introductory Hands-on Course for Physicians and Therapists"

1994 – 1995
- Residency Program Director

1991 – 1995 **Cardinal Hill Rehabilitation Hospital**
- Utilization Review Committee
- Dysphagia Committee
- Development of Dysphagia Survey mailed to all hospitals in Kentucky to establish areas of service/need
- Long Range Planning Committee – Stroke

1993 – 1995
- Research Committee, Chair

1996-2012 **University of Florida, College of Medicine**
- Medical Director, SpineCare Center 1996 – 09/2011
- UF Health Systems Worker's Compensation Provider Network Project Team – 08/1996

ADMINISTRATIVE ACTIVITY (Continued)
- Post-Acute Hospitalization Planning Committee – 09/1996
- Chair, Sub-Acute Rehabilitation Subcommittee – 09/1996
- HealthSouth Project Team – 09/1996
- Interim Chief Division of Physical Medicine and Rehabilitation, Department of Orthopaedics Surgery – 02/1997 – 07/1998
- Medical Staff Executive Committee – 07/1997
- Rehabilitation Medical Advisory Committee – Jul 1997
- Chair – Jul 1997
- Physiatry Steering Committee – May 1997
- Rehabilitation Operations Group – Feb 1997
- Chief, Division of Physical Medicine and Rehabilitation, Department of Orthopaedics and Rehabilitation – Jul 1998 – Sep 2011
- Advisory Board, Gator Sports Camp – Jul 1998
- VA Rehab Task Force – Jul 1998
- Program Director, PM&R Fellowship Program – July 1999 – Sep 2011
- Shands Pain Committee – Jul 2001 – 07/2003

- Shands Spinal Cord Injury Committee – July 2001 – July 2003
- Chair, Shands Pain Management Subcommittee – July 2004 – July 2008

02/97-2012 **Shands Rehab Hospital**

- Medical Director

07/01-2012 **Shands Rehab Hospital**

- Medical Director, Spinal Cord Injury Continuum of Care

1993-2005 **Commission on Accreditation of Rehabilitation Facilities (CARF)**

- Surveyor Training – Tucson, AZ – Jul 1993
- Site Survey; New Hampshire Rehabilitation Hospital;/Health South Concord, NH; November 1993
- National Advisory Committee – Outpatient Medical Rehabilitation – Tucson, AZ – March 1994
- Site Survey; Yonkers Rehab Center; Des Moines; IO; April 1994
- Site Survey; Holzer Medical Center Rehabilitation Unit; Gallipolis, OH; June 1994
- Site Survey; Union Memorial Hospital; Baltimore, MD; January 1995
- Site Survey; Rehab Institute of Chicago; Chicago, IL; May 1995
- Site Survey; Rehab Institute of Michigan; Detroit, MI; September 1995
- Site Survey; Stratton VA Medical Center, PM&R Services; Albany, NY; April 1996
- Site Survey; Coghlin Rehabilitation Hospital of the Medical College of Ohio; Toledo, OH; June 1996
- Site Survey; Magee Rehab Hospital; Philadelphia, PA; December 1996
- Site Survey; Edward Hines Jr VA Hospital; Hines, IL; June 1997
- Site Survey; Aultman Comprehensive Medical Rehabilitation Center; Canton, OH; December 1997
- Site Survey; Broken Arrow Rehabilitation; Broken Arrow, OK; February 1998
- Site Survey; St. Francis Medical Center, the Center for Physical Rehabilitation; Pittsburgh, PA; September 1998
- Site Survey; Doctors Hospital of Stark County Rehab Center; Masillon, OH; March 1999
- Site Survey; Barberton Citizens Hospital Rehabcare Center; Barberton, OH; May 1999
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ADMINISTRATIVE ACTIVITY (Continued)

- Site Survey; Rehabilitation Institute at Tennessee Christian Medical Center; Nashville, TN; November 1999
- Site Survey; St. Elizabeth Health Center Acute Rehab Unit; Youngstown, OH; May 2000
- Site Survey; Louis Stoke Cleveland Dept of Veteran Affairs medical Center; Cleveland, OH; June 2000
- Site Survey; Firelands Regional Health System; Sandusky, OH; October 2000
- Site Survey; Meridia Center for Rehabilitation and Pain Management; Euclid, OH; December 2000
- Site Survey; University of North Carolina Hospitals – Rehab Center, Chapel Hill; NC; August 2001
- Site Survey; Avante at Leesburg; Leesburg, FL; October 2001

- Site Survey; The Rehab Program at Hollywood Medical Center; Hollywood, FL; September 30-October 1,2002
- Site Survey; Marion General Hospital; Marion, OH; June 2003
- Site Survey; Middleton Regional Hospital/Inpatient Rehab Unit; Middleton, OH; June 2004
- Site Survey; Ohio Valley Rehabilitation Network, Inc.; Bridgeport, OH; August 2004

2012–2012 Surveyor Training – Tucson, AZ – Feb 2012

- Site Survey; Northeastern Rehabilitation at Heritage Hospital; Tarboro, NC; May 2012

1997-2012 **Florida Department of Labor & Employment Security, Division of Vocational Rehabilitation, Florida Brain and Spinal Cord Injury Program**

- Inpatient/Outpatient Rehabilitation Committee – Apr 1997
- Site Survey: Tampa General Rehabilitation Center – Dec 2000
- Site Survey: Lee Memorial Hospital, Ft. Myers, FL – May 2008

2001-2003 **University of North Texas Health Science Center, Texas College of Osteopathic Medicine**

- External Board of Scientific Counselors

HONORS

Undergraduate

- Sigma Sigma Sigma – National Biology Honorary Society
- Phi Eta Sigma – National Men's Freshman Honorary Society

Medical School

- Sigma Sigma Phi – National Osteopathic Honorary Society
- Outstanding Academics & Community Service Award, 1985
- Dean's Award for Outstanding Academic, Personal integrity, and Anticipated Contribution to the Field of Osteopathic Medicine, 1987
- Outstanding Clinical Student at OUCOM NE Ohio Regional Teaching Site, Brentwood Hospital, Warrensville Heights, OH, 1987

32.0 Internship

- Intern/Resident Research Paper Contest Winner (chosen by clinical faculty); Title: "Recognition and recovery from ankle sprains: a step-wise treatment and rehabilitation program."

Residency

- Senior Resident Academic Achievement Award, 1991

Academia

- Teacher of the Year (chosen by residents), Department of Rehabilitation Medicine, University of Kentucky, College of Medicine, 1991-1992

HONORS (Continued)

- Master Teacher Award for Leadership, University of Kentucky, College of Medicine, 1995
- Exemplary Teacher, College of Medicine, University of Florida, 2003-2004
- Distinguished Clinician Award, American Academy of Physical Medicine and Rehabilitation, 2010 (National)

VOLUNTEER PROFESSIONAL ACTIVITIES

Ohio High School Athletic Association

- On-site physician, Central Ohio District Basketball Tournament; Mar 1989, Mar 1990
- On-site physician, State Soccer Final; Nov 1989
- On-site physician, State Football Finals; Nov1989
- On-site physician, State Track Finals; Jun 1990, Jun 1991
- On-site physician, State Basketball Finals; Mar 1991

33.0 Ohio State Wheelchair Olympics

- On-site physician, May 1989, May 1990, May 1991

34.0 Ohio State Fair Golden Gloves Boxing Tournament

- On-site physician; Aug 1989

35.0 Great Ohio Bike Adventure

- On-site physician; Jun 1990

36.0 United States Olympic Committee (Drug Testing)

- Columbus Marathon, Columbus, OH; Nov 1988
- TAC/USA Track & Filed Junior National Championships, Columbus, OH; Jun 1989
- USA National Baseball Team, Millington, TN; Jun 1989
- USA National Karate Championships, Akron, OH; Feb 1990

Cardinal Hill Hospital

- Physician liaison for Stroke Support Group; Fall 1991 – 1996
- Live Television Interview – 21st Annual Telethon' Apr 1992
- Celebrity/physician 3-on-3 Kick-off, Downtown Showdown Shoot-out; May 1992

Kentucky Bluegrass Games

- On-site physician; Jul 1992, Jul 1993

Salvation Army Free Clinic, Lexington, KY

- Physician; Sep 1992, Nov 1992, May 1993, Aug 1993, Dec 1993, Feb 1994, Jan 1995, Apr 1995, Aug 1995, Sep 1995

TOPP Soccer Program

- Co-Director of the creation of local TOPP Soccer Program for kids with disabilities; 2006-2007

Shands Healthcare Marketing, Gainesville, FL

- Healthcast audio recording to be used on hospital website. Oct 2008

AOA/AOF iLEARN Mentor Exchange Program

- Offer guidance and wisdom to student doctors, interns, residents and DOs.

PROFESSIONAL AFFILIATIONS

American Academy of Physical Medicine and Rehabilitation
American Association Neuromuscular & Electrodiagnostic Medicine
American Osteopathic Association
American Osteopathic College of Physical Medicine and Rehabilitation
American Pain Society
American Society of Interventional Pain Physicians

American Spinal Cord Injury Association

PROFESSIONAL AFFILIATIONS (continued)

Association of Academic Physiatrists
Florida Osteopathic Medical Association
Florida Society of Physical Medicine and Rehabilitation
North American Spine Society
American Academy of Pain Management (2012)
American Academy of Pain Medicine (2012)

NATIONAL/STATE COMMITTEES

1992–Present **American Academy of Physical Medicine & Rehabilitation**

- Subcommittee on Electronic Enhancement of PM&R Educational Opportunities; 1992, 1993, 1994, 1995
- Liaison to Medical Education Committee; 1993
- Program Planning Committee, 1996-2007
- Chair, 2004 - 2007
- PASSOR Liaison; 2002 to 2010
- Pain Course Co-Chair; 2004 to 2006
- Awards Committee; 2008, 2009

Geriatric Special Interest Group

- Nominating Committee; 1995, 1996
- Presentation of Breakfast Focus Session at AAPM&R National Convention on Controversial Issues; 11/1992
- Survey on The use of Unconventional Medications and Treatments in Geriatric Rehabilitation; 10/1994

Manual Medicine Special Interest Group

- Chairman; 1995, 1996
- Co-Chairman National Program Committee; 1993, 1994
- Submissions for 1993
  - Manual Medicine Techniques in the Elderly
  - The Sacroiliac Joint and its Relationship to Low Back Pain
  - Mechanical Thoracic Pain – An Interdisciplinary Approach: the Integration of Manual Medicine and Myofascial Pain Concepts in Physiatric Practice
  - Submissions for 1994
  - Manual Medicine and Quality Management
  - The Use of Manual Medicine in Performing Artists
  - Manual Medicine Approach to Shoulder Pain: Adhesive Capsulitis, Neck, Scapula or Rib Dysfunction?
  - Exercise, Prescription as a Continuum of Manual Medicine
  - Application of Manual Medicine for the Young Physiatrist
- National Survey of Residency Programs to Determine Level and Source of Instruction of Manual Medicine
- National Survey of Special Interest Group Members to Produce a List of Physiatrists Willing to Teach Manual Medicine to Residents and Other Practitioners

- Special Interest Group Chairs Committee; 1994

Stroke and Neurological Diseases Rehabilitation Special Interest Group

- Review of Practice Parameter Paper on Venous Thromboembolism in Stroke; 03/1993

NATIONAL/STATE COMMITTEES (Continued)

Opioid REMS Task Force Planning Committee

- Chairman; 2012

1997-2003 **American Association of Electrodiagnostic Medicine**

- Journal Committee; 2001-2003
- Marketing & Public Relations Committee; 1998-2001

1997-2001 **American Board of Electrodiagnostic Medicine**

- Oral Board Examiner; 1997- 1998, 1999, 2000, 2001

2003-Present **American Spinal Cord Injury Association**

- Prevention Committee – 2003, 2004
- Membership Committee – 2003, 2004
- Program Committee – 2009-2012

1992-Present **Association of Academic Physiatrist**

- Review of Fellowship White Paper; 02/1993
- Education Committee; 1992, 1993, 1998
- Undergraduate Medical Education Committee; 1994-1997
- Principal Author of White Paper on Medical Student Education and PM&R; 1995, 1996
- Research Coordinators Council; 1994, 1996-1998
- Residency Program Directors Council; 1994, 1995

1992 – 1995 **Kentucky Academy of Physical Medicine and Rehabilitation**

- Education Committee; 1992-1995

1993-2005 **Commission on Accreditation of Rehabilitation Facilities (CARF)**

2012- - Site Surveyor; 1993-2005; 2012

- National Advisory Committee: Outpatient Medical Rehabilitation; 1994

1997-2012 **Florida Department of Labor and Employment Security, Division of Vocational Rehabilitation, Florida Brain and Spinal Cord Injury Program**

- Inpatient/Outpatient Rehabilitation Committee, 04/1997

2012-Present **American Academy of Pain Medicine**

- 2013 Annual Meeting Planning Committee

37.0

38.0 INVITED LECTURES

Feb 1990 - "Entrapment syndromes." The Ohio State University School of Allied Health Science, Columbus, OH

Sep 1990 - "Social Security Administration disability guidelines for the

musculoskeletal and neurologic systems." Rehabilitation Services Commission of Ohio, Bureau of Disability Determination, Adjudicator Training Classes, Columbus, OH

Nov 1990 - "Spinal manipulation and massage." The Ohio State University, Physical Medicine Course 736, Columbus, OH

Jan 1991 - "Spinal infection." The Ohio State University Department of Physical Medicine, Grand Rounds, Columbus, OH

- "Musculoskeletal and neurologic systems examination in relation to the Social Security Administration disability guidelines." University of Kentucky Department of Rehabilitation Medicine Grand Rounds, Lexington, KY

INVITED LECTURES (Continued)

June 1991 - "Social Security Administration disability guidelines for the musculo-skeletal and neurologic systems." Rehabilitation Services Commission of Ohio, Bureau of Disability Determination, Adjudicator Training Classes, Columbus, OH

Sep 1991 - "Spinal manipulation for low back pain." University of Kentucky Fourth Annual Rehabilitation Management Conference for the Primary Care Physician, Lexington, KY

Nov 1991 - "Multiple sclerosis: diagnosis, treatment and rehabilitation." Rockcastle County Hospital, Medical Staff Grand Rounds, Rockcastle, KY

Dec 1991 - "Medical complications of stroke." Veterans Medical Center Nursing Inservice Lexington, KY

Jan 1992 - "Complications of medications following central nervous system injury." Veterans Medical Center Therapy Inservice, Lexington, KY

- "What is physical medicine and rehabilitation?" University of Kentucky

- Department of Student Health, Grand Rounds, Lexington, KY

Mar 1992 - "Use of exercise in the elderly to enhance functional mobility." University of Kentucky, Department of Rehabilitation Medicine, Grand Rounds, Lexington, KY

- "Principles of cervical manipulation." Cardinal Hill Rehabilitation Hospital Physical Therapy Inservice, Lexington, KY

- "Use of exercise in the elderly to enhance functional mobility." University of Kentucky, CME Outreach Program at Carter Cave Resort Park, KY

April 1992 - "Introduction of physical medicine and rehabilitation: what does it have to offer you?"

University College of Osteopathic Medicine, Professional Counseling Week, Athens, OH

May 1992 - "Use of exercise in the elderly to enhance functional mobility." University of Kentucky, Department of Rehabilitation Medicine, Resident Research Day, Lexington, KY

June 1992 - "Diagnosis and treatment of cervical and lumbar radiculopathy." Veterans

Medical Center Therapy Inservice, Lexington, KY

Aug 1992 - "Use of exercise in the elderly to enhance functional mobility." University

of Kentucky and Sanders-Brown Center on Aging, The 9th Annual Summer Series on Aging, Lexington, KY

Sept 1992 - "Use of exercise in the elderly to enhance functional mobility." University of Kentucky, Fifth Annual Rehabilitation Management Conference for the Primary Care Physician, Lexington, KY

Oct 1992 - "Diagnosis and treatment of entrapment neuropathies." Veterans Medical Center, Therapy Inservice, Lexington, KY

- "Low back pain: diagnosis and aggressive conservative management." South Williamson Appalachian Regional Hospital Medical Staff Grand Rounds, South Williamson, KY

Dec 1992 - "Osteopathic medicine: its history and use." University of Kentucky Athletic Training Staff and Student Trainers Grand Rounds, Lexington, KY

- "Low back pain and spinal injury in athletes: causes, evaluation, treatment, and outcome." University of Kentucky Department of Rehabilitation Medicine Grand Rounds, Lexington, KY

Feb 1993 - "Medical complications following stroke." University of Kentucky 24th Annual Family Medicine and Primary Care Review, Lexington, KY

- Workshop on "Aggressive conservative management of back and neck pain." University of Kentucky 24th Annual Family Medicine & Primary Care Review, Lexington, KY

INVITED LECTURES (Continued)

Mar 1993 - "Falls in the elderly." University of Kentucky Division of Geriatrics and Sanders-Brown Center on Aging *Updates in Geriatrics*, Lexington, KY

May 1993 - "Medical complications following stroke." University of Kentucky 24th Annual Family Medicine and Primary Care Review, Lexington, KY

- Workshop on "Aggressive conservative management of back and neck pain." University of Kentucky 24th Annual Family Medicine & Primary Care Review, Lexington, KY

June 1993 - "The use of exercise in prevention and rehabilitation of falls and hip fractures." The Ohio Valley Appalachia Regional Geriatric Education Center Teleconference, Lexington, KY

Jul 1993 - "The use of exercise in prevention, rehabilitation, and outcome of falls and hip fractures." University of Kentucky Department of Rehabilitation Medicine, Grand Rounds, Lexington, KY

Aug 1993 - "Medical considerations and complications following common orthopedic procedures: total hip replacement, total knee replacement, repair of hip fracture, and the Ilizarov technique." Cardinal Hill Rehabilitation Hospital General Rehabilitation/ Orthopedic Update 1993, Lexington, KY

Sept 1993 - "Updates in the management of stroke." Cardinal Hill Rehabilitation Hospital Patient/ Family Stroke Support Group, Lexington, KY

- "Treatment of back pain in the elderly and following stroke." Cardinal Hill Rehabilitation Hospital Stroke Program Team Meeting, Lexington, KY

Oct 1993 - "Medical rehabilitation issues following stroke." Johnson Mathers Hospital Medical Staff Meeting, Carlisle, KY

- "New developments in the acute management of persons following stroke." Cardinal Hill Rehabilitation Hospital, *Stroke Update 1993*, Lexington, KY

Feb 1994 - Workshop on "Falls assessment." University of Kentucky 24th Annual Family Medicine and Primary Care Review, Lexington, KY

May 1994 - "Spinal injury in athletes: causes, evaluation, treatment, and outcome." University of Kentucky Department of Rehabilitation Medicine Grand Rounds, Lexington, KY

Jun 1994 - "Falls Assessment." Johnson Mathers Hospital Medical Staff Meeting, Carlisle, KY

- "The use of unconventional medications in geriatric rehabilitation." The Ohio State University Department of Physical Medicine and Rehabilitation Resident Farewell Day, Columbus, OH.

Jun 1994 - "Alternative uses of electromyography as a research tool." The Ohio State University Department of Physical Medicine and Rehabilitation Resident Farewell Day, Columbus, OH

- "Incorporating manual medicine into an exercise prescription." The Ohio State University Department of Physical Medicine and Rehabilitation Resident Farewell Day, Columbus, OH

July 1994 - "Enabling the elderly." University of Kentucky and Sanders-Brown Center on Aging, The 11th Annual Summer Series on Aging, Lexington, KY

- "Medical rehabilitation issues following stroke." Medical Staff Meeting, London, KY

Aug 1994 - "New CARF standards for comprehensive and subacute rehabilitation and new levels of rehabilitation care." University of Kentucky Dept of Physical Medicine and Rehabilitation Seventh Annual Rehabilitation Conference, *The Rehabilitation Continuum: From Hospital to Home*, Lexington, KY

INVITED LECTURES (Continued)

Sep 1994 - "The use of unconventional medication during geriatric rehabilitation." The Ohio State University Seventh Annual Update in Internal Medicine, Columbus, OH

- "The electromyographic and kinematic analysis of climbing activities in amputee farmers." Television Interview with Jerry Sanders, Channel 27, Lexington, KY

- "The use of ankle strengthening exercises to prevent falling in the elderly."

Television Interview with Jerry Sanders, Channel 27, Lexington, KY

Oct 1994 - "Preventing falls in farmers with disabilities." External Advisory

Committee of Southeast Center for Agricultural Health and Injury Prevention, Lexington, KY

- "Medical rehabilitation issues following stroke." East Cumberland Hospital Medical Staff Meeting, Columbia, KY
- "Stroke update: new developments in the acute management and rehabilitation of persons following stroke." Cardinal Hill Rehabilitation Hospital Stroke Update 1994, Lexington, KY

Dec 1994 - "Discussion of *the AHCPR Guidelines on the Management of Acute Low Back Problems*." Television Interview with Jerry Sanders, Channel 27, Lexington, KY

Feb 1995 - "Enabling the elderly." University of Kentucky 25th Annual Family Medicine and Primary Care Review, Lexington, KY

- "Muscle energy manipulation." Cardinal Hill Rehabilitation Hospital
  Dept of Physical Therapy Grand Rounds, Lexington, KY

Mar 1995 - "The aging athlete." University of Kentucky Dept of Orthopedics, Sports Medicine Grand Rounds, Lexington, KY

- "Structural diagnostic exam." University of Kentucky Dept of PM&R Course – *Clinical Osteopathic Manual Medicine: Introductory Hands-On Course for Physicians and Therapists*, Lexington, KY
- "Principles of vertebral motion." University of Kentucky Dept of PM&R Course*: Clinical Osteopathic Manual Medicine: Introductory Hands-On Course for Physicians and Therapists*, Lexington, KY

- "Layer palpation." University of Kentucky, Dept of PM&R*, Clinical Osteopathic Manual Medicine: Introductory Hands-On Course for Physicians and Therapists*, Lexington, KY
- "Segmental motion testing." University of Kentucky, Dept of PM&R, *Clinical Osteopathic Manual Medicine: Introductory Hands-On Course for Physicians and Therapists*, Lexington, KY
- "Functional indirect technique." University of Kentucky, Dept of PM&R, *Clinical Osteopathic Manual Medicine: Introductory Hands-On Course for Physicians and Therapists*, Lexington, KY.
- "Incorporating manual medicine into daily practice." University of Kentucky, Dept of PM&R, *Clinical Osteopathic Manual Medicine: Introductory Hands-On Course for Physicians and Therapists*, Lexington, KY

Apr 1995 - "Falls assessment." University of Kentucky, Division of Geriatrics and Sanders-Brown Center on Aging , *Updates in Geriatrics*, Lexington, KY

May 1995 - "Enabling the elderly." University of Kentucky 25th Annual Family Medicine and Primary Care Review, Lexington, KY

INVITED LECTURES (Continued)

- "A review of the *AHCPR Guidelines for Acute Low Back Problems*." University of Florida, Departments of Neurosurgery and Orthopedic Surgery Grand Rounds, Gainesville, FL

Jun 1995 - "A review of the *AHCPR Guidelines for Acute Low Back Problems*." Kentucky Osteopathic Medical Association Annual Meetings, Ft. Mitchell, KY

- "How to use the *AMA Guides for Disability and Impairment Ratings*." Kentucky Osteopathic Medical Association Annual Meetings, Ft. Mitchell, KY

Jul 1995 - "Pathophysiology and medical management of stroke." Appalachian Regional Hospitals Home Health Nursing Conference, Paintsville, KY

Aug 1995 - "A review of the *AHCPR Guidelines for Acute Low Back Problems.*" University of Kentucky Department of Physical Medicine and Rehabilitation Eighth Annual Rehabilitation Conference, Lexington, KY

Sep 1995 - "Use of exercise in the elderly." The Ohio State University Dept of Physical Medicine and Rehabilitation, EWJ Society Reunion, Columbus, OH

- "EMG/kinematic analysis of the hemiplegic shoulder." The Ohio State University Department of Physical Medicine and Rehabilitation, EWJ Society Reunion, Columbus, OH

- "Enabling the elderly." University of Kentucky, 25th Annual Family Medicine and Primary Care Review, Lexington, KY

Nov 1995 - "Nonoperative care: early physical therapy, injections, etc.; late pain and low back pain management; interventional blocks." The Center for Advanced Medical Education Spine Review Course, Chicago, IL

- "Postoperative care: acute and long-term rehabilitation; spinal cord injury/bracing; postoperative bracing." The Center for Advanced Medical Education Spine Review Course, Chicago, IL

Dec 1995 - "A review of the *AHCPR Guidelines for Acute Low Back Problems*." University of Kentucky, Department of Physical Medicine and Rehabilitation Grand Rounds, Lexington, KY

Feb 1996 - "A review of the *AHCPR Guidelines for Acute Low Back Problems.*" Shands Hospital Rehabilitation Services Grand Rounds, Gainesville, FL

Mar 1996 - "Diagnosis, treatment and care of patients with acute low back pain." University of Kentucky Offices of Continuing Pharmacy, Medical and Nursing Education, Bowling Green, KY

- "Diagnosis, treatment and care of patients with acute low back pain." University of Kentucky Offices of Continuing Pharmacy, Medical and Nursing Education, Owensboro, KY

- "Diagnosis, treatment and care of patients with acute low back pain." University of Kentucky Offices of Continuing Pharmacy, Medical and Nursing Education, Corbin, KY

- **"**Rehab of the acute CVA patient." University of Kentucky Department of Continuing Education, course on *Topics in Geriatric Medicine*, Lexington, KY

Apr 1996 - "Agency for Health Care Policy and Research *Guidelines for the Treatment of Acute Low Back Problems in Adults*: a review." American College of Occupational and Environmental Medicine Seminar, *The Physiatric Approach to Low Back Pain: Aggressive Nonsurgical Approach*, San Antonio, TX.

INVITED LECTURES (Continued)

- Return to work issues in occupational low back injuries.” American College of Occupational and Environmental Medicine Seminar, *The Physiatric Approach to Low Back Pain: Aggressive Nonsurgical Approach*, San Antonio, TX
- “Return to work issues in occupational neck injuries.” American College of Occupational and Environmental Medicine Seminar, *The Physiatric Approach to Neck Pain*, San Antonio, TX

May 1996
- “University of Florida SpineCare Program.” Radio Call in Program, Rock 104, Gainesville, FL
- “University of Florida SpineCare Program.” Noon News, Channel 20, Gainesville, FL

Jun 1996
- “Sacroiliac joint dysfunction: diagnostic evaluation and treatment.” Shands Hospital Physical Therapy Staff, Gainesville, FL

Aug 1996
- “University of Florida SpineCare Program.” Interview with Myro Munroe Noon News, Channel 20,Gainesville, FL

Jan 1997
- “Enabling the elderly.” Department of Veteran Affairs, Geriatric Conference, Gainesville, FL
- “Appropriate referrals to the SpineCare Clinic.” University of Florida, Department of Community Health & Family Medicine, Gainesville, FL

Feb 1997
- “Evaluation and treatment of acute spinal problems.” University of Florida, College of Medicine, Department of Rheumatology Grand Rounds, Gainesville, FL

May 1997
- “Occupational low back pain.” American College of Occupational and Environmental Medicine Conference, Safety Harbor, FL
- “Assessment and treatment of occupational neck pain.” American College of Occupational and Environmental Medicine Conference, Safety Harbor, FL

Jul 1997
- “Algorithmic approach to spinal interventions.” University of Florida, College of Medicine, Health and Human Performances, Gainesville, FL *Rehabilitation of the Spine Update ‘97.* Orlando, FL
- “Use of manual medicine in a comprehensive rehabilitation program.” University of Florida, College of Medicine, Health and Human Performances, Gainesville, FL *Rehabilitation of the Spine Update ‘97.* Orlando, FL
- “Medical interventions in rehabilitation.” Shands Rehab Hospital Staff, Gainesville, FL

Aug 1997
- “Manual medicine.” Kessler Institute for Rehabilitation, West Orange, NJ

Sep 1997
- “Non-surgical care (part 1).” Weekly Spine Conference, Departments of Neurosurgery and Orthopaedic Surgery, College of Medicine, University of Florida, Gainesville, Fl

Oct 1997
- “Evaluation and treatment of low back pain.”Orthopaedic Grand Rounds, DepartmenT of Orthopaedic Surgery, College of Medicine, University of Florida, Gainesville, FL
- “Evaluation and treatment of low back pain” and “Evaluation and treatment of neck pain.” Lecture to PA Students, College of Medicine, University of Florida, Gainesville, FL
- “What’s on your mind?” TV 20 panel, Gainesville, FL

Nov 1997 - "Evaluation and treatment of acute low back pain (part 1)."Family Practice Noon Conference, Shands @ AGH, Gainesville, FL

INVITED LECTURES (Continued)

Dec 1997 - "Evaluation and treatment of acute low back pain (part 2)." Family Practice Noon Conference, Shands @ AGH, Gainesville, FL

Jan 1998 - "A question of health." TV 20 Panel. Gainesville, FL

- "Non-surgical care (part 1)." Weekly Spine Conference, Departments of Neurosurgery and Orthopaedic Surgery, College of Medicine, University of Florida, Gainesville, FL
- "Evaluation and treatment of acute and chronic low back pain." PM&R Conference, Department of Orthopaedic Surgery, College of Medicine, University of Florida, Gainesville, FL

Mar 1998 - "Evaluation and treatment of neck pain."Family Practice Noon Conference, Shands @ AGH, Gainesville, FL

Apr 1998 - "Back pain in the athlete." Gainesville Sports Organizing Committee, Gainesville, FL

May 1998 - "Evaluation, classification, and rating of disability." PM&R Conference, Department of Orthopaedic Surgery, College of Medicine, University of Florida, Gainesville, FL

Jun 1998 - "Case presentations." Weekly Spine Conference, Departments of Neurosurgery and Orthopaedic Surgery, College of Medicine, University of Florida, Gainesville, FL

Aug 1998 - "Non-surgical care (part 2)." Weekly Spine Conference, Departments of Neurosurgery and Orthopaedic Surgery, College of Medicine, University of Florida, Gainesville, Fl

- "Advances and research related to the hemiplegic shoulder." Shands Rehab Hospital, Grand Rounds, Gainesville, FL

Aug 1998 - "Evaluation and maintenance of functional status in the elderly." Department of Veterans Affairs; Gainesville, FL

Nov 1998 - "Evaluation and treatment of low back pain" and "Evaluation and treatment of neck pain." Lecture to PA Students, College of Medicine, University of Florida, Gainesville, FL

Dec 1998 - "Spine CAMP." Weekly Spine Conference, Departments of Neurosurgery and Orthopaedic Surgery, College of Medicine, University of Florida, Gainesville, FL

- "Spine CAMP." Rehabilitation Medicine Associates. Gainesville, FL

Feb 1999 - "My aching back." Health Discoveries Conference, University of Florida, Gainesville, FL

May 1999 - "Learn how to stand up to back pain." With Eddy Duncan, M.D. and Patrick O'Connor, LPT. Public Lecture/Q&A, Illuminations. Gainesville, FL

Jun 1999 - "A Question of Health." TV 20 Panel. Gainesville, FL

Aug 1999 - "Initial visit and treatment – acute algorithm." Lecture to Family Practice Residents, College of Medicine, University of Florida, Gainesville, FL

Sep 1999 - "Evaluation and treatment of low back pain" and "Evaluation and treatment of neck pain." Lecture to PA Students, College of Medicine, University of Florida, Gainesville, FL

- "Enabling the elderly." Lecture to Geriatric Psychiatry Residents. VA Medical Center, Gainesville, FL

Feb 2000 - "Algorithmic approach to chronic spinal pain." Alachua County Pharmaceutical Association. Gainesville, FL.

Aug 2000 - "New strategies in the treatment of pain." Family Practice Noon Conference,
College of Medicine, University of Florida, Gainesville, FL

Sep 2000 - "Non-surgical management of back pain." Internal Medicine Grand Rounds.
College of Medicine, University of Florida, Gainesville, FL

INVITED LECTURES (Continued)

- "Occupational low back pain" and "Assessment and treatment of occupational neck pain." Lectures to PA Students, College of Medicine, University of Florida, Gainesville, FL

Jan 2001 - "Management of low back pain in the athlete." With Ephraim Brenman,D.O.
Sports Medicine Conference, College of Medicine, University of Florida, Gainesville, FL

May 2001 - "Chronic low back pain." Medicine Noon Conference, College of Medicine,
University of Florida, Gainesville, FL

- "Exercise therapy for the spine. Part 1." Anesthesia Pain Group, College of Medicine, University of Florida, Gainesville, FL

- "Exercise therapy for the spine. Part 2." Anesthesia Pain Group, College of Medicine, University of Florida, Gainesville, FL

May 2001 - "Opioids for chronic pain: Outcomes and clinical dilemmas." With Michael Robinson, Ph.D. Pain Interest Group. College of Medicine, University of Florida, Gainesville, FL

- "My aching back." National Association of Retired Federal Workers. Gainesville, FL

Sep 2001 - "Non-surgical management of back pain." Internal Medicine Grand Rounds.
College of Medicine, University of Florida, Gainesville, FL

- "Occupational low back pain" and "Assessment and treatment of occupational neck pain." Lectures to PA Students, College of Medicine, University of Florida, Gainesville, FL

Oct 2001 - "What is an osteopath?" Introduction to Profession of Medicine Series. College of Medicine, University of Florida, Gainesville, FL

- "Exercise therapy for the spine." Physical Therapy Inservice at Illuminations. Gainesville, FL.

Dec 2001 - "Exercise and manipulation" AND "Use of manual medicine in a comprehensive rehabilitation program." Department of Anesthesiology, College of Medicine, Gainesville, FL

Apr 2002 - "EMG Case Studies." University of Florida, Department of Orthopaedics & Rehabilitation Spine Conference, College of Medicine, Gainesville, FL

38.1.1 May 2002 - "Pain Management Strategies." ENT Department Morning Conference,

38.1.2 University of Florida, College of Medicine, Gainesville, FL

- "Pain Management Strategies." Neurosurgery Department Morning
- Conference, University of Florida, College of Medicine, Gainesville, FL

July 2002 - "Other Uses of Zanaflex." Lakeside Occupational Medicine Group.

38.1.3 Tampa, FL

July 2002 - "Rehabilitation of the Stroke Patient." Family Practice Residents, University of Florida, College of Medicine, Gainesville, FL

Dec 2002 - "Pain Assessment: A Review of Pain Algorithms." Shands Physical Therapists. University of Florida, Gainesville, FL

- "Conservative Back Care." Department of Orthopaedics and Rehabilitation,
- Spine Conference. University of Florida, College of Medicine, Gainesville, FL

Feb 2003 - "Chronic Low Back Pain." Health Psychology Graduate Students. Department of Clinical Psychology, University of Florida, College of Health Professions, Gainesville, FL

INVITED LECTURES (Continued)

Mar 2003 - "Implementing the Guidelines for Opioid Pharmacotherapy." Jansen Pharmaceutical
Roundtable, Gainesville, FL

38.1.4 Apr 2003 - "Implementing the Guidelines for Opioid Pharmacotherapy."

38.1.5 Jansen Pharmaceutical Roundtable. Gainesville, FL

38.1.6 Jul 2003 - "Implementing the Guidelines for Opioid Pharmacotherapy."

38.1.7 Jansen Pharmaceutical Roundtable. Gainesville, FL

Oct 2003 - "Rehabilitation of the Stroke Patient" and "Occupational Low Back Pain." (with Kalman, A.D., Rehab Psychology Class, University of Florida, College of Health Professions, Gainesville, FL

- "Put That Back Pain Behind You!" (with Kalman, A.D. and Shay, T.) Public Lecture/ Q&A, Magnolia Park Rehab Center. Gainesville, FL

38.1.8 Nov 2003 - "Rehabilitation Following Cervical Mylopathy." University of Florida,

38.1.9 Department of Orthopaedics & Rehabilitation Spine Conference, College of Medicine, Gainesville, FL

Jan 2004 - "Occupational Low Back Pain" AND "Assessment and Treatment of Occupational Neck Pain." Lectures to PA Students, College of Medicine, University of Florida, Gainesville, FL

Mar 2004 - "Osteopathic Medicine." PM&R Interest Group. University of Florida, College of Medicine, Gainesville, FL

Mar 2005 - "Put That Back Pain Behind You!" (with Kalman, A.D. and Shay. T.) Public Lecture/Q&A, Orthopaedics & Sports Medicine Institute, University of Florida, Gainesville, FL

- "Common Neuropathic Pain Disease States in Primary Care." Sponsored by Embryon. Presented to Research Triangle Primary Care Physicians, Raleigh, NC

Apr 2005 - "Working With Your Patient in Managing Neuropathic Pain." Presented to Cincinnati Area Primary Care Physicians. Cincinnati, OH

May 2005 - "Post-Op Pain Management." Grand Rounds, Department of Neurosurgery, University of Florida, Gainesville, FL

May 2005 - Whole Patient Management in Neuropathic Pain: Evidence and Experience. "Evidence-Based Treatment of Neuropathic Pain. Pri-Med Update sponsored by Embryon. Toledo, OH

June 2005 - "Common Neuropathic Pain Disease States in Primary Care." Common Chronic Pain Conditions Confronting the Primary Care Provider. Pennsylvania Convention Center. Sponsored by Embryon. Philadelphia, PA

Oct 2005 - Improving Outcomes for Patients with Chronic Pain. "Chronic Pain: Its Causes and Clinical Manifestations." Presented to Pri-Med Regional Satellite Symposium. Sponsored by Embryon. Baltimore, MD

Mar 2006 - Whole Patient Management in Neuropathic Pain: Evidence and Experience. "Management of Comorbidities: Evidence for Success." Pri-Med Update sponsored by Embryon. Melville, NY

Apr 2006 - Whole Patient Management in Neuropathic Pain: Evidence and Experience. "Management of Comorbidities: Evidence for Success." Pri-Med Update sponsored by Embryon. Charlotte, NC

May 2006 - Modern Management of Spinal Disorders. "Medical Management of Back Pain." Sponsored by Riverside Methodist Hospital. Columbus, Ohio.

INVITED LECTURES (Continued)

Jun 2006 - Whole Patient Management in Neuropathic Pain: Evidence and Experience. "Evidence-Based Treatment of Neuropathic Pain. Pri-Med Update sponsored by Embryon. Jacksonville, FL

Sep 2006 - Update in Management of Spinal Pain Problems. Rochester Spine Study Group, University of Rochester, Rochester, NY

Sep 2006 - Management of Comorbitities: Evidence for Success. (Clinical Experience in Managing Neuropathic Pain: Managing Comorbitities in Neuropathic Pain Case Study II) Pri-Med Update sponsored by Embryon. Philadelphia, PA

Feb 2007 - Indications and Outcomes of Rehabilitation Following Trauma. Multidisciplinary Trauma Conference, Shands Hospital. Gainesville, FL

May 2007 Opiate Therapy, Narcotic Patient Contracts and Chronic Pain Management. (Managing Chronic Pain: Clinical, Ethical & Lawful Solutions.) The Medical Educational Council of Pensacola in joint sponsorship with Area One Florida Medicaid, Emerald Coast Health Alliance and Health First Network, Inc. Andrews Institute Conference Center, Gulf Breeze, FL

Sep 2007 Spine Course. "Medical Management of Low Back Pain." Sponsored by the Department of Orthopaedics and Rehabilitation, University of Florida, Gainesville, FL

Sep 2007 Issues Related to Shands Rehab Hospital and Shands Healthcare. Presented at Florida Group Practice Board Meeting, Gainesville, FL

Apr 2008 Update on Electromyography. Orthopaedics and Physical Medicine and Rehabilitation Spine Conference

Mar 2010 Neck and Cervical Spine. Physician Assistant Program, University of Florida, Gainesville, FL

Mar 2010 Rehabilitation Following Trauma – Indications and Outcomes. Multidisciplinary Trauma Conference, University of Florida, Gainesville, FL

Jun 2010 Management of Spinal Pain and Injury – Case Studies. 2010 PM&R Residents Graduating Class, Ohio State University, Columbus, OH

Opioid Analgesics. 2010 PM&R Residents Graduation Class, Ohio State University, Columbus, OH

So You're Ready to Be a Physiatrist? 2010 PM&R Residents Graduating Class, Ohio State University, Columbus, OH

Mar 2011 **Atchison, JW.** "Low Back and SI Pain in Runners." Running Medicine 2011, Innovation & Practice Through Science." University of South Florida and University of Florida. Gainesville, FL.

Sep 2011 Hamilton S, Nguyen W, Kennedy DJ, **Atchison JW.** Four Case Presentations. Pain Connections Journal Club, Gainesville, FL.

Jan 2012 **Atchison, JW.** "Pain Management." Grand Rounds. Northwestern University - Feinberg School of Medicine, Department of Physical Medicine and Rehabilitation,
The Rehabilitation Institute of Chicago. Chicago, IL.

Mar 2012 AHMA "Back Pain" Seminar to medical students. University of Florida, College of Medicine, Gainesville, FL

"Principles of Pain Management" Geriatric Fellowship Noon Conference. University of Florida/North Florida/South Georgia Veterans Health System, Geriatric Research Education & Clinical Centers, Gainesville, FL

INVITED LECTURES (Continued)

September 2014 67th Annual Ward E. Perrin Clinical Refresher Course, "ER/ LA Opioid REMS: Achieving use while improving patient care". Lombard, IL

Feb 2015 CRPS Grand Rounds. Anesthesia Pain Center, Stanford University, Palo Alto, CA.

Rational Pharmacology. Division of PM&R, Stanford University, Palo Alto, CA.

38.1.10 PRESENTATIONS AT PROFESSIONAL MEETINGS

Nov 1989 - **Atchison JW**, Pelligrino M, Herbers, P, and Matkovic V. "Hepatic Encephalopathy mimicking stroke." APM&R National Convention, San Antonio, TX; Poster; Nov 1989.

Oct 1990 - **Atchison JW,** Rindler J, Haddock D, Saneda D, and Pease W. "Rehabilitation following arsenic toxicity." AAPM&R National Convention, Phoenix, AZ. Platform

- **Atchison JW** and Waylonis G. "Manipulative medicine." AAPM&R National Convention, Phoenix, AZ. Video
- **Atchison JW**, Wachendorf J, Gribble M, Corrigan J., and Mysiw J. Hyponatremia associated cognitive deficits in a traumatic brain injured
- population." AAPM&R National Convention, Phoenix, AZ. Poster

Feb 1991 - **Atchison JW**, McDonough N, Shamir D, Powers J, Waylonis G, and Pease W. "Electrodiagnostic medicine during PM&R residency training." AP National Convention, San Diego, CA. Poster

Nov 1992 - **Atchison JW**, Salcido R, Noble L, Marshall R, and Walker M. "Use of exercise in the elderly to enhance mobility." AAPM&R National Convention, San Francisco, CA. Platform

Nov 1992 - Salcido, R, Schleenboker RE, **Atchison JW**, and Gershkoff, AM. "Controversies in geriatric rehabilitation case management." AAPM&R National Convention, San Francisco, CA. Breakfast Focus Session; Sponsored by Geriatrics SIG

- Salcido R, Farrage JR, Lindsey R, and **Atchison JW**. Painful compression of the lateral antebrachial cutaneous nerve in C5-C6 quadriplegia." AAPM&R National Convention, San Francisco, CA. Platform (presented by Farrage JR).

Nov 1993 - Farrage JR, Salcido R, **Atchison JW**, and Haglund B. "Compression syndrome involving lateral antebrachial cutaneous nerve in high level of quadriplegia." AAPM&R National Convention, Miami Beach, FL. Platform (presented by Farrage JR).

- Mein EA, Gilliar W, and **Atchison JW** (faculty). "The sacroiliac joint and its relationship to low back pain." AAPM&R National Convention, Miami Beach, FL. Breakfast Focus Session; Sponsored by Manual Medicine SIG
- **Atchison JW** , Mein EA, Gillar W, and Gershkoff A (faculty). "Manual medicine techniques in the elderly." AAPM&R National Convention, Miami Beach, FL. Workshop Leader; Sponsored by Geriatrics and Manual Medicine SIGs

Farrage J, Salcido R, **Atchison JW**, Stanos SP, and Stracener WA. "The efficacy of impedance plethysmography for detecting deep venous thrombosis in patients following stroke at a free-standing rehabilitation hospital." AAPM&R National Convention, Miami Beach, FL. Poster

Atchison JW, Ikai T, Kraft GH, Lan N, and Salcido R. "Kinematic and EMG firing patterns regarding normal and hemiparetic shoulder function." Course on Futuristic Models for

38.1.11 **PRESENTATIONS AT PROFESSIONAL MEETINGS (Continued)**

Rehabilitation of the Hemiparetic Arm. AAPM&R National Convention, Miami Beach, FL

Jan 1994 - Newman RL, **Atchison JW**, and Klim GV. "The perceived need for increased training in manual medicine by residents in PM&R." AAP National Convention, Naples, FL. Poster

Oct 1994 - Holmes T, **Atchison JW**, Gilliar WG, and Gershkoff A (faculty). "Manual medicine approach to shoulder pain: adhesive capsulitis, neck, and scapula or rib dysfunction." AAPM&R National Convention, Anaheim, CA. Workshop; Sponsored by Manual Medicine SIG and Geriatrics SIG

- **Atchison JW** , Glassman J, and Holmes T. "Exercise prescription as a continuum of manual medicine" AAPM&R National Convention, Anaheim, CA. Workshop Leader; Sponsored by Manual Medicine SIG

Oct 1994 - Gilliar WG, **Atchison JW**, and Mein EA (faculty). "The use of manual medicine in performing artists." AAPM&R National Convention, Anaheim, CA. Workshop; Sponsored by Manual Medicine SIG and Performing Arts SIG

- **Atchison JW**, Hecht JS, and Biundo, JJ. "Shoulder pain and dysfunction in the disabled person: the hemiplegic shoulder -- anatomy and kinesiology." AAPM&R National Convention, Anaheim, CA. Course; Sponsored by Geriatrics SIG, Arthritis SIG, Stroke SIG

- **Atchison JW**, Nickerson RB, McDowell SM, and Turner HS. "The use of a university-based student health clinic to promote and educate PM&R residents." AAPM&R National Convention, Anaheim, CA. Platform

Mar 1995 - Nickerson RB, VanHoose J, Hayes D, and **Atchison JW**. "Hiccups associated with lateral medullary syndrome." AAP National Convention, Phoenix, AZ. Poster

Apr 1995 - **Atchison JW**, Stine R, Sampson J, Oeffinger D, Shapiro R, and Salcido R. Electromyographic and kinematic analysis of the hemiplegic shoulder in comparison to healthy elderly males." Seventh World Congress of the International Rehabilitation Medicine Association, Washington, DC. Platform

May 1995 - **Atchison JW**. "Unique uses of manual medicine: a series of case reviews." American Osteopathic College of Rehabilitation Medicine National Meetings, Chicago, IL. Platform

Nov 1995 - **Atchison JW**, Belfie AH, Robbins HJ, and Alfaro A. "Neck pain: prevalence, etiology, and pathological changes associated with acute and chronic

neck pain." AAPM&R National Convention, Orlando, FL. Course on Neck Pain and Cervical Manipulation. Sponsored by Manual Medicine SIG

- **Atchison JW**, Noble LE, Salcido RM, Herrel P, and Donofrio JC. "Maintenance of Improved strength and functional mobility 18 months following an isotonic quadriceps exercise program." AAPM&R National Convention, Orlando, FL. Platform

Nov 1995

- **Atchison JW**, Simpson L, Knapp L, Oeffinger D, and Mainous III A. "Increased isotonic quadriceps strength following stroke with a six week exercise program." AAPM&R National Convention, Orlando, FL. Platform
- **Atchison JW**, Oeffinger D, Johnson D, Simpson C, and Salcido, RM. "Increased isotonic ankle dorsiflexor strength in a healthy elderly population with an eight week exercise program." AAPM&R National Convention, Orlando, FL. Platform
- Kuhlman KA, **Atchison JW**, Gay RE, Hennessey WJ, and Robbins HF (faculty). "Application of manual medicine for the young physiatrist."AAPM&R National

38.1.12 **PRESENTATIONS AT PROFESSIONAL MEETINGS (Continued)**

Convention, Orlando, FL. Resident Physician Council Workshop; Sponsored by Manual Medicine SIG.

- Kirsteins A, **Atchison JW** and Hecht JS (faculty). "Shoulder pain following stroke." AAPM&R National Convention, Orlando, FL. Stroke and Neurologic Diseases Rehabilitation SIG
- Stoll ST and **Atchison JW**. "Comparison of primary care physicians and patient's attitudes toward manual medicine." AAPM&R National Convention, Orlando, FL. Platform; (presented by Stoll ST)

Oct 1996

- Bilkey W, Holmes T, **Atchison JW**, Stoll ST, and Belfie A (faculty). "Foolproof techniques for the manual medicine beginner." AAPM&R National Convention, Chicago, IL.Workshop; Sponsored by Manual Medicine SIG
- Glassman J, Holmes T, **Atchison JW**, and Belfie A (faculty). "Manual medicine approach to headaches which originate in the cervical spine."AAPM&R National Convention, Chicago, IL. Workshop; Sponsored by Manual Medicine SIG
- Tolchin R, Mein, E, Stoll S, **Atchison JW**, Dreyfuss, PH Magaziner E, Guisto J, and Tomski M. "Combination techniques in manual medicine." AAPM&R National Convention, Chicago, IL. Course on Facet Joint Injections and Manual Medicine. Manual Medicine SIG Forum
- **Atchison JW**, Nickerson R, and Tharp D. "Innovations in exercise prescriptions: videotaping manual medicine treatment programs to be used at home or with a therapist." AAPM&R National Convention, Chicago, IL. Poster
- **Atchison JW**, Stoll ST, and McDowell S. "Manipulation under local anesthesia: lumbar sympathetic blocks followed by high-velocity, low-amplitude treatment." AAPM&R National Convention, Chicago, IL. Poster
- **Atchison JW**, Knapp L, Oeffinger D, Mainous III A, and Salcido RM.

"The risk of post-stroke falls based on timed 'up & go' testing and isotonic quadriceps weight lifting." AAPM&R National Convention, Chicago, IL. Platform

- Knapp L, **Atchison JW**, Shapiro R, Salcido RM, and Abbas J. "Electromyographic and kinematic analysis of the painful hemiplegic shoulder before and after subscapularis motor point block"□□AAPM&R National Convention, Chicago, IL. Platform

Feb 1997 - Knapp L, **Atchison JW**, Oeffinger P, Bay S, Lang R, and Salcido R. "The Effects of an isotonic ankle dorsiflexor strengthening program on falling in a healthy elderly population." □AAP National Convention, Colorado Springs, CO. Platform

Nov 1997 - **Atchison JW**, Tran AH, and Nickerson RB. "The availability of manual medicine instruction in PM&R training programs." AAP National Convention, Las Vegas, NV. Poster

- Bilkey W, Holmes T, **Atchison JW**, Stoll ST, Belfie A, and Tomski M (faculty). "Foolproof techniques for the manual medicine beginner." AAPM&R Annual Assembly, Atlanta, GA. Workshop; Sponsored by Manual Medicine SIG
- **Atchison JW**, Holmes T, Belfie A, Stoll S, and Tomski M (faculty). "Diagnosis of low back pain secondary to SI joint or piriformis dysfunction." AAPM&R Annual Assembly, Atlanta, GA. Workshop; Sponsored by Manual Medicine SIG
- Glassman J, Holmes T, **Atchison JW**, Belfie A, and Tomski M (faculty). "Manual medicine approach to headaches which originate in the cervical

38.1.13 **PRESENTATIONS AT PROFESSIONAL MEETINGS (Continued)**

spine." AAPM&R National Convention, Atlanta, GA. Workshop; Sponsored by Manual Medicine SIG.

- **Atchison JW**, Holsbeke M, and Jacob RP. "An unusual case demonstrating the use of L1 and L2 selective nerve root blocks." AAPM&R National Convention, Atlanta, GA. Poster

Nov 1998 - **Atchison JW.** "Advantages of oral narcotics in chronic spine pain." AAPM&R National Convention, Seattle, WA

Feb 1999 - Otis J, Robinson, ME, and **Atchison JW**. "Long term narcotics for chronic pain: cognitive, neuromotor, and pain response." University of Florida, College of Health Profession' Research Fair. Gainesville, FL. Poster

- **Atchison JW**. "Efficacy of manipulative treatment." Association of Academic Physiatrists Annual Meeting. San Antonio, TX

Mar 2000 - Robinson MJ and **Atchison JW**. "Recent reports about using opiates to treat chronic pain." Association of Academic Physiatrists 36th Annual Meeting. San Diego, CA (Presented by Michael J. Robinson, Ph.D.)

Nov 2000 - Robinson M, Waxenberg L, Otis J, Atchison J, Radson E, and Lafayette-Lucey A. Effectiveness of oral opioids for chronic non-malignant pain. American Pain Society 19th Annual Scientific Meeting. Atlanta, GA.

Apr 2001 - **Atchison JW.** "Pain management: Everybody's business." Rehab 2001:

From discovery to recovery. Gainesville, FL

Nov 2001 - Otis JD, Robinson ME, and **Atchison JW**. "The comparison of multidimensional pain measures: Use of a multitrait multimethod matrix technique." 35th Annual Meeting of the Association for the Advancement of Behavior Therapy. Poster Session. Philadelphia, PA

Mar 2002 - **Atchison JW.** "Teaching manual medicine techniques to residents." Association of Academic Physiatrists Annual Meeting. Las Vegas, NV

Jul 2002 - **Atchison JW.** "The treatment of acute musculoskeletal injury." Annual Meeting of the Florida Society of the American College of Osteopathic Family Physicians. Orlando, FL

Nov 2002 - **Atchsion JW.** "Cervical spine manipulation." American Academy of Physical Medicine and Rehabilitation Annual Assembly. Orlando, FL

Mar 2003 - Robinson ME, **Atchison J W,** Bulcourf BB, Lafayette-Lucey A, and Berger J. "Predicting adherence to pain rehabilitation: Patient and provider predictors." 39th Annual Meeting Association of Academic Physiatrists. Ft. Lauderdale, FL

Jan 2004 - **Atchison JW**. "What's up with PM&R?" Annual Disorders of the Spine. Sponsored by University of South Florida, Vancouver, BC, Canada

- **Atchison JW.** "Post-Op Pain Management." Annual Disorders of the Spine. Sponsored by University of South Florida, Vancouver, BC, Canada

Apr 2004 - **Atchison JW**. "Geriatric issues." Session A. Emerging Concepts in the Diagnosis and Treatment of Pain: An Intensive and Comprehensive Review. American Academy of Physical Medicine and Rehabilitation. New Orleans, LA

Apr 2004 - **Atchison JW**. "Pain issues of pregnancy." Session B. Emerging Concepts in the Diagnosis and Treatment of Pain: An Intensive and Comprehensive Review. American Academy of Physical Medicine and Rehabilitation. New Orleans, LA

38.1.14 **PRESENTATIONS AT PROFESSIONAL MEETINGS (Continued)**

- **Atchison JW**. "Modalities - traditional." Session 4. Emerging Concepts in the Diagnosis and Treatment of Pain: An Intensive and Comprehensive Review. American Academy of Physical Medicine and Rehabilitation. New Orleans, LA
- **Atchison JW**. "Complementary and alternative medicine (CAM) – Manual TX." Session 6. Emerging Concepts in the Diagnosis and Treatment of Pain: An Intensive and Comprehensive Review. American Academy of Physical Medicine and Rehabilitation. New Orleans, LA
- **Atchison JW**. "Acute, trauma-related issues." Session 18 Emerging Concepts in the Diagnosis and Treatment of Pain: An Intensive and Comprehensive Review. American Academy of Physical Medicine and Rehabilitation. New Orleans, LA

May 2004 - Hirsh AT, Chung SK, O'Brien EM, George SZ, Cianfrini L, **Atchison**

JW, Gremillion H, Waxenberg LB, and Robinson ME. "Does the catastrophizing subscale of the coping strategies questionnaire provide unique information regarding the pain experience?" 2nd Joint Scientific Meeting of the American Pain Society and Canadian Pain Society (poster session). Vancouver, BC, Canada

May 2004 - Edwards PS, Riley JL, Brown JL, George SZ, Fillingim RB, Waxenberg LB, **Atchison JW**, Wittmer V, and Robinson MF. Patients success criteria predicted by distress and expectation for treatment." 2nd Joint Scientific Meeting of the American Pain Society and Canadian pain Society (poster session). Vancouver, BC, Canada

May 2004 - Brown JL, Edwards PS, George SZ, Fillingim RB, Waxenberg LB, **Atchison JW**, Gremillion HA, and Robinson ME. "Patient centered success criteria and expectations for treatment: A comparison of spine pain and facial pain patients." 2nd Joint Scientific Meeting of the American Pain Society and Canadian Pain Society (poster session). Vancouver, BC, Canada

Jun 2004 - Dannecker EA, Robinson ME, and **Atchison JW**. "Sex differences in RPE and pain during eccentric contractions. " American College of Sports Medicine. 51st Annual Meeting. Indianapolis, IN

- **Atchison JW**. "Manual medicine: Is there a role in acute and chronic low back pain?" Controversies in Pain Management Course. Rehab Institute of Chicago, Chicago, IL

Jul 2004 - **Atchison JW**. "Sacroiliac and piriformis dysfunction." Charlotte Institute of Rehabilitation. Carolinas Medical Center. Charlotte, NC

Sep 2004 - Thomas P and **Atchison JW.** "Coming to terms with the concept of "medical necessity" in medical rehabilitation." American Congress of Rehabilitation and American Society of Neurorehabiltation Joint Conference. Ponte Verda Beach, FL

Oct 2004 - **Atchison JW.** "The Burden of Neuropathic Pain: A Multidisciplinary Approach Yields a Successful Outcome." American Academy of Physical Medicine and Rehabilitation Annual Meeting. Sponsored by the Dannemiller Memorial Foundation and Embryon, and is supported by an unrestricted educational grant from Pfizer Inc. Phoenix, AZ

Nov 2004 - **Atchison JW**. "Manual medicine: An evidence based medicine review." American Association of Electrodiagnostic Medicine 51st Annual Scientific Meeting. Savannah, GA

Jan 2005 - "Discogenic Pain: Initial Treatment and When to Refer to a Surgeon." Annual Disorder of the Spine. Sponsored by University of South Florida, Vancouver, BC, Canada

38.1.15 **PRESENTATIONS AT PROFESSIONAL MEETINGS (Continued)**

- "Discogenic Pain: Post-op and Chronic Pain Management." Annual Disorder of the Spine. Sponsored by University of South Florida, Vancouver, BC, Canada

May 2005 - **Atchison JW**. "Modalities – traditional and non-traditional, acupuncture

and manipulation." Session 9. *Emerging Concepts in the Diagnosis and Treatment of Pain: An Intensive and Comprehensive Review.* American Academy of Physical Medicine and Rehabilitation. New Orleans, LA

- **Atchison JW.** "Opioid pharmacology II." Session 21. *Emerging Concepts in the Diagnosis and Treatment of Pain: An Intensive and Comprehensive Review.* American Academy of Physical Medicine and Rehabilitation. New Orleans, LA
- **Atchison JW.** "Diagnosis of neck pain." Session 30. *Emerging Concepts in the Diagnosis and Treatment of Pain: An Intensive and Comprehensive Review*. American Academy of Physical Medicine and Rehabilitation. New Orleans, LA
- **Atchison JW.** "Treatment of low back pain." Session 37. *Emerging Concepts in the Diagnosis and Treatment of Pain: An Intensive and Comprehensive Review.* American Academy of Physical Medicine and Rehabilitation. New Orleans, LA
- **Atchison JW.** "Pain in medical diseases." Session P1*. Emerging Concepts in the Diagnosis and Treatment of Pain: An Intensive and Comprehensive Review*. American Academy of Physical Medicine and Rehabilitation. New Orleans, LA

May 2005

- **Atchison JW**. "Acute, trauma-related issues." Session P2. *Emerging Concepts in the Diagnosis and Treatment of Pain: An Intensive and Comprehensive Review.* American Academy of Physical Medicine and Rehabilitation. New Orleans, LA
- **Atchison JW.** "Post-op pain management." Session P3. *Emerging Concepts in the Diagnosis and Treatment of Pain: An Intensive and Comprehensive Review*. American Academy of Physical Medicine and Rehabilitation. New Orleans, LA
- **Atchison JW**. "Geriatric issues." Session P7. *Emerging Concepts in the Diagnosis and Treatment of Pain: An Intensive and Comprehensive Review.* American Academy of Physical Medicine and Rehabilitation. New Orleans, LA

Jun 2005

- **Atchison JW**. "Modalities – traditional and non-traditional, acupuncture and manipulation." Session 7. *Emerging Concepts in the Diagnosis and Treatment of Pain: An Intensive and Comprehensive Review.* American Academy of Physical Medicine and Rehabilitation. San Francisco, CA
- **Atchison JW.** "Non-opioid analgesics: NSAIDs, and COX-2 inhibitors, corticosteroids, antispasmodics." Session 14. *Emerging Concepts in the Diagnosis and Treatment of Pain: An Intensive and Comprehensive Review.* American Academy of Physical Medicine and Rehabilitation. San Francisco, CA
- **Atchison JW.** "Opioid pharmacology II." Session 19. *Emerging Concepts in the Diagnosis and Treatment of Pain: An Intensive and Comprehensive Review*. American Academy of Physical Medicine and Rehabilitation. San Francisco, CA
- **Atchison JW.** "Treatment of low back pain." Session 33. *Emerging Concepts in the Diagnosis and Treatment of Pain: An Intensive and Comprehensive Review.* American Academy of Physical Medicine and Rehabilitation. San Francisco, CA
- **Atchison JW.** "Diagnosis of neck pain." Session 30. *Emerging*

Concepts in the Diagnosis and Treatment of Pain: An Intensive and Comprehensive Review. American Academy of Physical Medicine and Rehabilitation. San Fransisco, CA

38.1.16 **PRESENTATIONS AT PROFESSIONAL MEETINGS (Continued)**

Oct 2005 - **Atchison JW.** "Improving Outcomes for Patients with Chronic Pain." *Chronic Pain: Its Causes and Clinical Manifestations.* Pri-Med Regional Satellite Symposium. Baltimore, MD

- **Atchison JW.** "Thoracic Spine – Role of Manual Therapy." American Academy of Physical Medicine and Rehabilitation 66th Annual Assembly. Philadelphia, PA.

Jan 2006 - **Atchison JW.** "Sacroiliac and Piriformis Dysfunction." 18th Annual Disorders of the Spine. Sponsored by University of South Florida, Vancouver, BC, Canada

Jan 2006 - **Atchison JW.** "Update on Electromyography." 18th Annual Disorders of the Spine. Sponsored by University of South Florida. Vancouver BC, Canada

Nov 2006 - Glassman JH, Holmes TG, **Atchison JW,** Garrison SJ**.** "Principles of Manual Medicine and Rehabilitation." American Academy of Physical Medicine and Rehabilitation. Honolulu, Hawaii

Jan 2007 - **Atchison JW.** "Physiatrists: Cervical Session." 19th Annual Disorders of the Spine. Sponsored by University of South Florida, Vancouver, BC, Canada.

- **Atchison JW.** "Physiatrists: Pharmacologic Management." Sponsored by University of South Florida, Vancouver, BC, Canada

- **Atchison JW.** "Physiatrists: Thoraco-Lumbar Session." Sponsored by University of South Florida, Vancouver, BC, Canada

- **Atchison JW.** "Pain Issues in the Elderly." Sponsored by University of South Forida, Vancouver, BC, Canada

Mar 2007 - **Atchison, JW.** "Opiate Therapy, Narcotic Patient Contracts and Chronic Pain Management." American College of Osteopathic Family Physicians 44th Annual Convention, Kissimmee, Florida

Sep 2007 - **Atchison JW.** "Topical Analgesics in the Management of Neuropathic Pain." Principles of Effective Pain Management: Focus on Topical Analgesia. A CME Symposium, AAPM&R 68th Annual Assembly. Sponsored by ENDO Pharmaceuticals. Boston, MA.

Atchison JW. "Course 514, PASSOR: Therapeutic Exercise for Lumbar Spine Disorders. AAPM&R 68th Annual Assembly, Boston, MA

Jan 2008 - **Atchison JW. "**New Post-Op Pain Management." 20th Annual Disorders of the Spine. Sponsored by the University of South Florida. Vancouver, BC, Canada

- **Atchison JW.** "Evidence Based Evaluation and Treatment of Back Pain." Sponsored by the University of South Florida. Vancouver, BC, Canada

Nov 2010 - Glassman J, Holmes T, **Atchison JW,** Gay R, Schlinger M, Silverman J. "Principles of
Manual Medicine." American Academy of Physical Medicine and Rehabilitation. Seattle, WA

Nov 2010 - **Atchison, JW.** "Cervical Spine Mechanics – Muscle Energy Techniques." Principles of Manual Medicine. Seattle, WA

Nov 2010 - **Atchison, JW.** "Principles of Mobilization with Impulse: High Velocity/Low Amplitude Thrust Technique." Principles of Manual Medicine. Seattle, WA

Nov 2010 - **Atchison, JW.** "Spine Care for the Obese Patient." American Academy of Physical Medicine and Rehabilitation. Seattle, WA

Nov 2011 - **Atchison, JW.** "Best Papers". American Academy of Physical Medicine and Rehabilitation. 72nd Annual Assembly of AAPM&R. Orlando, FL

- **Atchison, JW.** "Manual Treatment of SI." Principles of Manual Medicine. 72nd Annual Assembly of AAPM&R. Orlando, FL

38.1.17 **PRESENTATIONS AT PROFESSIONAL MEETINGS (Continued)**

- **Atchison, JW.** "Cervical Manipulation." Principles of Manual Medicine. 72nd Annual Assembly of AAPM&R. Orlando, FL

April 2013 - **Atchison, JW**. "New Sacroiliac Joint Interventional Procedure: A shot in the Dark or New Techniques that work? AAPM's 29th Annual Meeting. Fort Lauderdale, FL

- **Atchison, JW**. "Structural and Functional Examination of the Cervical and Thoracic Spine". AAPM's 29th Annual Meeting. Fort Lauderdale, FL
- **Atchison, JW**. "Epidemiology and Pathway to develop Lumbar Spinal Stenosis". AAPM's 29th Annual Meeting. Fort Lauderdale, FL

May 2013 - Gagnon C, **Atchison JW**, Stanos SP. "Patients' Perception of Change Following an Interdisciplinary Pain Management Program. American Pain Society Annual Meeting. New Orleans, LA

October 2013 - **Atchison, JW**. " New Approaches and Treatment Consideration in Mild Moderate Musculoskeletal Pain". AMCP Symposium, San Antonio, TX.

March 2014 - **Atchison, JW**. "Applying Interdisciplinary Principles of Pain Management to Persons With knee OA". Management of Knee Osteoarthritis: What is Missing from the Treatment Guidelines. AAPM 30th Annual Meeting, Phoenix, AZ.

- **Atchison, JW**. "What not to Miss When the Young Patient Presents with Low Back Pain". Updates in Chronic Pain Management in the Adolescent Population. AAPM 30Th Annual Meeting, Phoenix, AZ.
- **Atchison, JW**. : "Osteopathic Manipulation (Muscle Energy) Techniques for Lumbar, Sacral and Pelvis Dysfunction: Demonstration". Physical Examination and Differentiation of Lumbar Spine, SI Joint and Hip Joint Problems. AAPM 30th Annual Meeting, Phoenix, AZ.

November 2014- **Atchison, JW**. "Manual Medicine for Low Back Pain". AAPM&R 2014 Annual Assembly, San Diego, CA.

- **Atchison, JW**. "Interdisciplinary Functional Restoration Pain Programs". AAPM&R 2014 Annual Assembly, San Diego, CA.
- **Atchison, JW.** "How Much is Enough…Interdisciplinary Treatment

Time?"AAPM&R 2014 Annual Assembly, San Diego, CA.

- **Atchison, JW**. "Manual Treatment for Cervical Pain and Headache". AAPM&R 2014 Annual Assembly, San Diego, CA.

March 2015
- **Atchison, JW**. " Structural and Functional Examination of the Cervical and Thoracic Spine". AAPM 31st Annual Meeting, Washington, DC 2015.
- **Atchison, JW**. "The Most Common Complaints of Knee Pain that Present in the office". AAPM 31st Annual Meeting, Washington, DC 2015.

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Atchison J, Pelligrino M, Herbers P, and Matkovic V, "Hepatic encephalopathy mimicking stroke. A case Report." Am J Phys Med Rehab 1992;71(2):114-118.

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PEER-REVIEWED PUBLICATIONS (Continued)

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Atchison JW. "Manual medicine SIG: neck pain and cervical manipulation. Neck pain: relevance, etiology, and pathological changes associated with acute and chronic neck pain." 57th Annual Assembly Am Acad Phys Med Rehab, 1995; 1058-1062.

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ABSTRACTS

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ABSTRACTS (Continued)

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GRANT PROPOSALS: PRINCIPAL INVESTIGATOR

Apr 1992 - University of Kentucky, College of Medicine Research Fund. "Improved functional mobility through exercise following stroke."

Jul 1992 - Retirement Research Foundation, Chicago, IL. "Improved functional mobility through exercise following stroke." Funded for $35,848 (1/93-1/94). No cost extension to 1/96.

Mar 1993 - University of Kentucky, College of Medicine Research Fund. "Isotonic ankle dorsiflexor strengthening to improve functional mobility and decrease falls in an elderly population with borderline-safe ambulation skills" Funded for $7,200.

- Kentucky NIH/EPSCOR. "Isotonic ankle dorsiflexor strengthening to improve functional mobility and decrease falls in an elderly population with borderline-safe ambulation skills."

GRANT PROPOSALS: CO-INVESTIGATOR

Apr 1993 - University of Kentucky, Medical Center Research Fund. "Isotonic ankle dorsiflexor strengthening to improve functional mobility and decrease falls in an elderly population with borderline-safe ambulation skills." Funded for $8,000.

Feb 1992 - Sanders-Brown Center on Aging, Lexington, KY. "Electromyographic and kinematic activity of the normal and hemiparetic shoulder after stroke." Funded for $10,000.

May 1992 - National Institute for Occupational Safety and Health, Centers for Disease Control. In association with the University of Kentucky Department of Preventive Medicine and Environmental Health. "Cooperative Agreement Program for Centers for Agricultural Research, Education and Disease and Injury Prevention - kinematic motion analysis of climbing by amputee farmers." Funded for $33,677.

Jan 1993 - Retirement Research Foundation, Chicago, IL. In association with Randall Schleenbaker, M.D., University of Kentucky, Dept of Rehabilitation Medicine. "Muscle strengthening as an intervention to improve recovery from near falls in the elderly."

Mar 1993 - Whitaker Foundation, Mechanicsburg, PA. "Effects of continuous Passive motion and neuromuscular electrical stimulation in the prevention of shoulder sequela of stroke." Initial Submission: Oct 1992. Revision.

Oct 1994 - National Institute of Health, Department of Health and Human Services, Washington, DC. In association with Nancy Stiles, M.D., University of Kentucky, Dept of Internal Medicine and Geriatrics. "Trial of occupational therapy for elders in primary care." Initial submission Resubmitted Oct 31, 1994.

Feb 1996 - Department of Health and Human Services, Public Health Service, Washington, DC. In association with Dr. Alexander Hadjipavlou, Department of Orthopaedics, University of Texas at Galveston Medical Branch. "Port 2: chronic low back pain."

Oct 1997 - National Institute of Mental Health, Washington, DC. In association with Michael Robinson, Ph.D., University of Florida, Dept of Clinical Psychology. "Depression and clinical pain perception." Funded

- National Institute of Health, Washington, DC. In association with Michael Robinson, Ph.D., University of Florida, Dept of Clinical Psychology. "Sex and gender role influences in pain and analgesia." Funded

- National Institute of Health, Washington, DC. With MichaelRobinson, PhD. "Pain and Depression." $103,000.

Jun 2001 - National Institute of Health, Washington, DC. With Michael Robinson, PhD. "Effect of Long Term Opioid Use for Chronic Pain."

Feb 2002 - National Institute of Health, Washington, DC. With Michael Robinson, PhD. "Effect of Long Term Opioid Use for Chronic Pain."

Jan 2003 - National Institute of Health, Washington, DC. With Michael Robinson, PhD. "Patient Centered Outcomes."

Jan 2004 - National Institute of Health, Washington, DC. "Locomotor experience applied post-stroke (LEAPS). With Pamela W. Duncan, PhD, et al. (SRH is a proposed study site.)

Feb 2004 - National Institute of Health, Washington, D.C (R01). With MichaelRobinson, PhD and Steve George, PhD. "Pain treatment decisions: Influence of sex, race, and age."

Aug 2004 - Foundation for Physical Therapy. With Steve George, PhD. "Efficacy of slump stretch treatment: A pilot randomized trial."

Sep 2006 - National Institute of Health/NINR, Washington, D.C. With Michael Robinson, PhD. "Pain Rehabilitation: Patient Centered Outcomes."

2006 - National Institute of Health. Robinson ME, Atchison JW, et al. "Mechanisms of Neural Mobilization for Chronic Pain."

Sep 2008 - National Institute of Health/NINR, Washington, D.C. With Michael Robinson, PhD. "Pain Treatment Decisions: Influence of Sex, Race and Age." (9/1/2008 – 6/31/2012)

IRB PROPOSALS: PRINCIPAL INVESTIGATOR

May 1992 - University of Kentucky IRB# 92-00090. "Improved functional mobility through exercise in a stroke survivor population."

Mar 1992 - University of Kentucky IRB# 93-00086. "Isotonic ankle dorsiflexor strengthening to improve functional mobility and decrease falls in an elderly population with borderline-safe ambulation skills."

Mar 1993 - University of Kentucky IRB# 93-00049. "Improved physical mobility through exercise."

May 1993 - University of Kentucky IRB# 93-00139. "Electrodiagnostic evaluation of the lateral antebrachial cutaneous nerve following spinal cord injury."

Oct 1994 - University of Kentucky IRB# 94-22056. "Weight bearing status at the

time of admission to a rehabilitation hospital following orthopedic procedure."

Feb 1995 - University of Kentucky IRB# 95-22008. "A survey of physical medicine and rehabilitation faculty in academic training programs to determine needs and interest in manual medicine."

Mar 1995 - University of Kentucky IRB. "Electromyographic and kinematic activity of the hemiplegic shoulder before and after subscapularis motor point block."

May 2002 - University of Florida IRB# 336-02 (now IRB 1-2004). "Efficacy of supported standing in spinal cord injury during acute inpatient rehabilitation – A pilot study."

Sep 2003 - University of Florida IRB# 2348-2003. "Progress in rehabilitation following orthopaedic injury correlated to analgesic medications prescribed: A comparison of patients in 1996 to 2001."

IRB PROPOSALS: CO-INVESTIGATOR

Feb 1993 - University of Kentucky IRB# 93-22010. "Manual medicine questionnaire for rehabilitation medicine residents."

Jun 1993 - University of Kentucky IRB# 93-30092. "Electromyographic and kinematic activity of the normal and hemiparetic shoulder after stroke." .

Jul 1998 - University of Florida IRB# 233-94. "Depression and clinical pain perception. With Michael Robinson, PhD and Patrick O'Connor PT.

May 1998 - University of Florida IRB# 122-1998. "Sex differences in emotional response to pain." With Michael Robinson, PhD.

Aug 2002 - University of Florida IRB# 421-2002. "Pain rehabilitation: patient centered outcomes." Michael Robinson, PhD, Fillingim, Roger B.; Waxenberg, Lori B. PhD.

42.0 Jun 2003 - University of Florida IRB# 83-2003. "Chronic analgesic medication for the treatment of chronic pain." With Michael Robinson, PhD.

- University of Florida IRB# 116-2003. "Behavioral interventions for chronic low back pain." With Steve George, PhD and Michael Robinson, PhD.

Jul 2003 - University of Florida IRB# 350-2003. 'Pain rehabilitation: reliability testing of the patient centered outcomes questionnaire." With Michael Robinson, PhD

IRB PROPOSALS: CO-INVESTIGATOR (Continued)

- University of Florida IRB# 327-2003. "Fear of movement/anxiety disorder related to knee osteoarthritis." With Steve George, PhD and Michael Robinson, PhD

2007 - University of Florida IRB# 595-2007. "Rehabilitation and Therapy Outcomes in Patients with Lumbar Disorders." (Co-I)

2008 - University of Florida WIRB 2008. "A Multi-center, Double-blind, Randomized Parallel-Group, Placebo Controlled Phase 2 Study of Once-Daily Subcutaneous Methylnaltrexone (MNTX) in the Treatment of Opioid-Induced Constipation During Rehabilitation After Orthopedic Procedures." (Sub-I)

- National Institute of Health RO3 (collaborator) HK Vincent, PI. "Resistance exercise effects on fear avoidance beliefs and physical function in obese, older adults with chronic low back pain (in second review, NIAMS NIH subsection)

CONTINUING MEDICAL EDUCATION

Feb 1992 - Association of Academic Physiatrists National Meeting, Orlando, FL

Aug 1992 - "9th Annual Summer Aging Series." Saunders-Brown Center on Aging, Lexington, KY

Sep 1992 - "Geriatric rehabilitation issues." University of Kentucky Office of Continuing Medical Education, Lexington, KY

- Kentucky Medical Association/Kentucky Academy of PM&R Meetings, Louisville, KY

Oct 1992 - American Association of Electrodiagnostic Medicine National Meetings, Charleston, SC

Nov 1992 - American Association of Physical Medicine & Rehabilitation National Meetings, San Francisco, CA

Feb 1993 - "Bloodborne Pathogens." University of Kentucky. Lexington, KY

Mar 1993 - "Updates in geriatrics." University of Kentucky Office of Continuing Medical education and Sanders-Brown Center on Aging, Lexington, KY

May 1993 - PM&R in the 21st century." Bruce Gans. Kentucky Academy of PM&R Spring Meetings, Midway, KY

May 1993 - Kentucky Osteopathic Medical Association Meetings, Louisville, KY

- "Use of new generation calcium channel blockers." Barry McLain, MD, UAB. Kentucky Horse Park, Lexington, KY

Jun 1993 - "Stepwise use of anticonvulsant medications." J. John Dotson, MD, St. Louis University. Bravo Pitinos. Lexington, KY

Jul 1993 - "Surveyor Training." Commission on Accreditation of Rehabilitation Facilities, Tucson, AZ

Jul 1993 - "Alzheimer's disease: theory, treatment and research." Bill Pert, MD, Vanderbilt University, Nashville, TN, New Orleans House

Sep 1993 - Kentucky Medical Association/Kentucky Academy of PM&R Meetings, Louisville, KY

Oct 1993 - "Stroke and related disorders – new approaches and practical solutions." National Stroke Association '93 Symposium, Lexington, KY

Nov 1993 - American Association of Physical Medicine and Rehabilitation National Meetings, Miami Beach, FL

CONTINUING MEDICAL EDUCATION (Continued)

- "Principles of manual medicine in physical medicine and rehabilitation." Michigan State University, College of Osteopathic Medicine Course. Miami Beach, FL

Jan 1994 - Association of Academic Physiatrists National Meetings, Naples, FL

Apr 1994 - Seventh World Congress of The International Rehabilitation Medicine Association, Washington, DC
- "Introduction to problem based learning for geriatrics preceptors." University of Kentucky, Lexington, KY
May 1994 - Kentucky Osteopathic Medical Association Annual Meetings. Louisville, KY
Sep 1994 - Kentucky Medical Association/Kentucky Academy of PM&R Meetings. Louisville, KY
Oct 1994 - American Academy of Physical Medicine and Rehabilitation National Meeting. Anaheim, CA
Dec 1994 - "The use of oral medications in pain Management." Douglas Kennedy, MD, Private Practice Anesthesia Pain Management, Lexington, KY
Mar 1995 - Association of Academic Physiatrists National Meetings. Phoenix, AZ
Apr 1995 - "Updates in geriatrics." University of Kentucky Office of Continuing Medical Education and Sanders-Brown Center on Aging. Lexington, KY
Jun 1995 - "PM&R in the 21st Century." Kentucky Academy of PM&R Spring Meetings. Shelbyville, KY
- Kentucky Osteopathic Medical Association Annual Meetings, Ft. Mitchell, KY
Sep 1995 - EWJ Society Reunion, The Ohio State University, Columbus, OH
Nov 1995 - American Association of Physical Medicine and Rehabilitation National Meetings, Orlando, FL
- Comprehensive Spine Review Course, Chicago, IL
Jan 1996 - Seventh Annual Osteopathic Winter Conference, Clearwater Beach, FL
Feb 1996 - Association of Academic Physiatrist National Meetings, Las Vegas, NV
- "Diagnosis and treatment of osteoporosis." University of Florida, Gainesville, FL
Apr 1996 - "The physiatric approach to neck pain." American College of Occupational and Environmental Medicine Meetings, San Antonio, TX
Oct 1996 - American Association of Physical Medicine and Rehabilitation National Meetings, Chicago, IL
Nov 1996 - "New treatments in acute ischemic stroke." University of Florida, Gainesville, FL
Apr 1997 - "Managing rehabilitation care by using critical pathways." Rehabilitation Foundation, Inc., Chicago, IL
May 1997 - "Assessment and treatment of neuromuscular conditions in the work place."
American College of Occupational and Environmental Medicine, Orlando, FL
Jun 1997 - "Accreditation standards for medical staff." Joint Commission on Accreditation of healthcare Organizations. Falmouth, MS
Aug 1997 - "Manual medicine." Kessler Institute for Rehabilitation, West Orange,NJ

CONTINUING MEDICAL EDUCATION (Continued)

Oct 1997 - "Orthopaedic Grand Rounds."

University of Florida, Department of Orthopaedic Survey, Gainesville, FL

Nov 1997 - "Domestic violence education update." University of Florida, Department of Orthopaedic Survey, Gainesville, FL

- Annual Scientific Assembly of the American Association of Physical Medicine and Rehabilitation, Atlanta, GA

Jan 1998 - "9th Annual Osteopathic Winter Seminar." St. Petersburg, FL

Feb 1998 - Association of Academic Physiatrists Annual Meeting, San Antonio, TX

Apr 1998 - "3-D CT of congenital scoliosis." Dr. Charles H. Bush, Orthopaedic Grand Rounds. University of Florida, Department of Orthopaedic Surgery, Gainesville, FL

May 1998 - "Current advances in spinal cord injury rehabilitation." American Osteopathic College of Rehabilitation Medicine. Lake Buena Vista, FL

Sep 1998 - "Avascular necrosis of the hip." Orthopaedic Grand Rounds. University of Florida, Department of Orthopaedics and Rehabilitation, Gainesville, FL

Oct 1998 - American Association of Electrodiagnostic Medicine Annual Meeting. Orlando, FL

Nov 1998 - Annual Scientific Assembly of the American Association of PhysicalMedicine and Rehabilitation, Seattle, WA

- "Proximal humerus fractures treated with arthroplasty." Orthopaedic Grand Rounds. University of Florida, Department of Orthopaedics and Rehabilitation, Gainesville, FL

Jan 1999 - "The historical developments in total knee arthroplasty." Orthopaedic Grand Rounds. University of Florida, Department of Orthopaedics and Rehabilitation, Gainesville, FL

Feb 1999 - Association of Academic Physiatrists 1999 Annual Meeting. Orlando, FL

May 1999 - "Kinematics of the knee and its implication for total knee prosthesis design." Orthopaedics Grand Rounds. University of Florida, Department of Orthopaedics and Rehabilitation, Gainesville, FL

Jul 1999 - "19th Annual Convention and National Family Practice Update." Florida Society American College of Osteopathic Family Physicians. Orlando, FL

Nov 1999 - "14th Annual Meeting." North American Spine Society. Chicago, IL

- "Treatment of open tibia fracture." Orthopaedic Grand Rounds. University of Florida, Department of Orthopaedics and Rehabilitation, Gainesville, FL

Jan 2000 - "Synthetic calcium phosphates in orthopaedic surgery: HA-coated implants and skeletal substitute materials." Orthopaedic Grand Rounds. University of Florida, Department of Orthopaedics and Rehabilitation, Gainesville, FL

Oct 2000 - "Motion Analysis." Orthopaedic Grand Rounds. University of Florida, Department of Orthopaedics and Rehabilitation, Gainesville, FL

Nov 2000 - "Failed back surgery and adjacent segment disease." Orthopaedic Grand Rounds. University of Florida, Department of Orthopaedics and Rehabilitation, Gainesville, FL

- "Annual Meeting." American Academy of Physical Medicine and Rehabilitation.
San Francisco, CA.

Mar 2001 - Orthopaedic Grand Rounds. University of Florida, Department of Orthopaedics and Rehabilitation. Gainesville, FL

Apr 2001 - Orthopaedic Grand Rounds. University of Florida, Department of Orthopaedics and Rehabilitation. Gainesville, FL

CONTINUING MEDICAL EDUCATION (Continued)

May 2001 - Orthopaedic Grand Rounds. University of Florida, Department of Orthopaedics and Rehabilitation. Gainesville, FL

- "Annual Meeting." American Spinal Injury Association. Long Beach, CA.

Jun 2001 - "CARF 101: Blueprint for success. Building a strong foundation in medical rehabilitation." June 13-15, 2001. Dallas, TX

- "33rd Annual Meeting." Southern Society of Physical Medicine and Rehabilitation.
New Orleans, LA

Nov 2001 - "Medical Directors Training Academy." National Association of Managed Care Physicians. Charlotte, NC.

43.0 Jan 2002 - "13th Annual Osteopathic Winter Seminar."

44.0 Pinellas County Osteopathic Medical Society.

- Orthopaedic Grand Rounds.
- University of Florida, Department of Orthopaedics and Rehabilitation. Gainesville, FL

May 2002 - "Microsurgery." Orthopaedic Grand Rounds.
University of Florida, Department of Orthopaedics and Rehabilitation.
Gainesville, FL

45.0 Sep 2002 - "Thrombosis prophylaxis: new strategies for an old problem."

46.0 Orthopaedics & Rehabilitation Grand Rounds, University of Florida,

47.0 Department of Orthopaedics and Rehabilitation. Gainesville, FL

Nov 2002 - American Academy of Physical Medicine and Rehabilitation Annual Assembly.
Orlando, FL

Mar 2003 - "39th Annual Meeting Association of Academic Physiatrist, Ft. Lauderdale, FL

May 2003 - "Appropriate opioid pharmacotherapy for chronic pain management." Discovery International. Gainesville, FL

Jul 2003 - "Comprehensive pain board symposium." University of Wisconsin Medical School, Madison, WI

Sep 2003 - "Interventional pain management symposium." American Society of Interventional Pain Physicians. Washington, DC

Nov 2003 - American Academy of Physical Medicine and Rehabilitation Annual Assembly. Chicago, IL

Feb 2004 - Florida Osteopathic Medical Association 101st Annual Meeting, Ft. Lauderdale, FL

Apr 2004 Emerging concepts in the diagnosis and treatment of pain: An intensive and comprehensive review. American Academy of PM&R. New Orleans, LA

May 2004 - 30th Annual Scientific Meeting of the American Spinal Injury Association. Denver, CO

Oct 2004 - American Academy of Physical Medicine and Rehabilitation Annual Assembly. Phoenix, AZ

Nov 2004 - American Association of Electrodiagnostic Medicine. 51st Annual Scientific Meeting, Savannah, GA

Jan 2005 - University of South Florida 17th Annual Disorders of the Spine Course. Whistler, Canada

Mar 2005 - Alachua County Medical Society Foundation. We Care Program (patient care). Gainesville, FL

Apr 2005 University of Florida, Department of Orthopaedics and Rehabilitation. Medical Grand Rounds. Gainesville, FL

CONTINUING MEDICAL EDUCATION (Continued)

May 2005 Emerging concepts in the diagnosis and treatment of pain: An intensive and comprehensive review. American Academy of PM&R. New Orleans, LA

Jun 2005 Emerging concepts in the diagnosis and treatment of pain: An intensive and comprehensive review. American Academy of PM&R. San Francisco, CA

Sep 2005 University of Florida, Department of Orthopaedics and Rehabilitation. Medical Grand Rounds. Gainesville, FL

2005 Florida Osteopathic Medical Association Mid-Year Seminar. Tampa, FL

Oct 2005 American Academy of Physical Medicine and Rehabilitation Annual Assembly. Philadelphia, PA

Jan 2006 University of South Florida 18th Annual Disorders of the Spine Course. Whistler, Canada

Mar 2006 University of Florida, Department of Orthopaedics and Rehabilitation. Medical Grand Rounds. Gainesville, FL

May 2006 University of Florida, Department of Orthopaedics and Rehabilitation. Medical Grand Rounds. Gainesville, FL

Jun 2006 American Spinal Cord Injury Association/ISCoS Global Spinal Cord Injury Conference. Boston, MA

Nov 2006 American Academy of Physical Medicine and Rehabilitation Annual Assembly. Honolulu, HI

Nov 2006 Orthopaedics & Rehabilitation Medical Grand Rounds. University of Florida. Gainesville, FL.

Jan 2007 19th Annual Disorders of the Spine Disorder of the Spine Course. Whistler, Canada.

Jan 2007 Multidisciplinary Trauma Conference. University of Florida College of Medicine. Gainesville, FL.

May 2007 Managing Chronic Pain: Clinical, Ethical & Lawful Solutions. The Medical Educational Council of Pensacola. Gulf Breeze, FL.

May 2007 33rd Annual Scientific Meeting, American Spinal Injury Association, Tampa, FL.

Sep 2007 Florida Osteopathic Medical Association Mid-Year Seminar, Tampa, FL.

Sep 2007 American Academy of Physical Medicine and Rehabilitation 2007 Annual Assembly. Boston, MA.

Jan 2008 20th Annual Disorders of the Spine Disorder of the Spine Course. Whistler, Canada

Feb 2008 University of Florida, Department of Orthopaedics And Rehabilitation Medical Grand Rounds, Medical Errors from a Spinal Perspective. Gainesville, FL.

Mar 2008 University of Florida, Department of Orthopaedics and Rehabilitation. Medical Grand Rounds. Gainesville, FL

Jun 2008 American Spinal Injury Association 2008 Annual Meeting. San Diego, CA

Jan 2009 University of Florida, Department of Orthopaedics and Rehabilitation. Medical Grand Rounds. Gainesville, FL

Sep 2009 Florida Osteopathic Mid-year Seminar. Tampa, FL.

Oct 2009 American Academy of Physical Medicine and Rehabilitation 2009 Annual Assembly. Austin, TX

Nov 2010 American Academy of Physical Medicine and Rehabilitation 2010 Annual Conference. Seattle, WA

Nov 2010 American Academy of Physical Medicine and Rehabilitation – Manual Medicine (Faculty) Seattle, WA

CONTINUING MEDICAL EDUCATION (Continued)

Jul 2011 American College of Osteopathic Family Physicians 31st Annual Convention.

Sep 2011 9th Annual Medical Rehabilitation Conference/American Medical Rehabilitation Providers Association. South Beach, FL

Nov 2011 American Academy of Physical Medicine and Rehabilitation 2011 Annual Conference. Orlando, FL

Feb 2012 Florida Osteopathic Medical Association 109th Annual Convention

Jan 2014 25th Annual Osteopathic Winter Seminar, Pinellas County Osteopathic Medical Society (PCOMS). Florida

April-May 2014 The 33rd Annual Scientific Meeting of the American Pain Society. Tampa, FL

March 2015 31st AAPM Annual Meeting. Washington, DC

CONTINUING MEDICAL EDUCATION – WRITTEN MATERIAL

Jan 1992 - The Medical Letter and the Yale School of Medicine, Continuing Medical Education Program. Exam #25

Jun 1992 - American Association of Electrodiagnostic Medicine Training Program Self-Assessment Examination

Jan 1993 - The Medical Letter and the Yale School of Medicine, Continuing Medical Education Program. Exam #27

Jul 1993 - The Medical Letter and the Yale School of Medicine, Continuing Medical Education Program. Exam #28

Jul 1994 - The Medical Letter and the Yale School of Medicine, Continuing Medical Education Program. Exam #30

Sep 1994 - "HIV and the health care worker." University of Washington, School of Medicine, Office of Continuing Medical Education.

Dec 1994 - "Amyotrophic lateral sclerosis." American Association Electrodiagnostic Medicine Case Report #5

Jan 1995 - The Medical Letter and the Yale School of Medicine, Continuing Medical Education Program. Exam #31

Feb 1995 - "Diseases associated with excess motor unit activity." American Association of Electrodiagnostic Medicine Mimimonograph #44

- "Monomelic amyotrophy." American Association of Electrodiagnostic Medicine Case Report #28

Dec 1995 - "Intraoperative monitoring of peripheral and cranial nerves." American Association of Electrodiagnostic Medicine Minimonograph #42

- "Neuromuscular problems in the performing arts." American Association of Electrodiagnostic Medicine Minimonograph #43

Jun 1996 - "Instrumentation and measurement in electrodiagnostic medicine." American Association of Electrodiagnostic Medicine Minimonograph #16

Jul 1996 - "Prolonged paralysis after neuromuscular blockade." American Association of Electrodiagnostic Medicine Case Report #29

- "The early development of electromyography." American Association of Electrodiagnostic Medicine Minimonograph #45

CONTINUING MEDICAL EDUCATION – WRITTEN MATERIAL (Continued)

Oct 1996 - The Medical letter and the Yale School of Medicine Continuing Medical Education Program Exam #33

- "Multifocal motor neuropathy." American Association of Electro-diagnostic Medicine Case Report #30

Mar 1997 - Neurogenic muscle hypertrophy." American Association of Electro-diagnostic Medicine Minimonograph #46

Mar 1997 - "Single-fiber electromyography." American Association of Electro-diagnostic Medicine Case Report #25

- "Diabetic amyotrophy." American Association of Electrodiagnostic Medicine Case Report #13

Sep 1997 - "Normative data in electrodiagnostic medicine." American Association of Electrodiagnostic Medicine Minimonograph #47

Nov 1997 - The Medical Letter and the Yale School of Medicine, Continuing Medical Education Program. Exam #35

Jan 1998 - "HIV/AIDS update: a self-study course for primary health care professionals." University of Florida, Office of Continuing Medical Education, Gainesville.

- "Autonomic nervous system testing." American Association of Electro-diagnostic Medicine Minimonograph #48

May 1998 - "The electrodiagnosis of carpal tunnel syndrome." American Association of Electrodiagnostic Medicine Minimonograph #26

Oct 1998 - "Somatosensory evoked potential." American Association of Electrodiagnostic Medicine Minimonograph #19

Oct 1999 - "Nerve injury associated with hip arthroplasty." American Association of Electrodiagnostic Medicine Case Report #32

- "1998 AAEM Training Program Self-Assessment Examination."

Jan 1999 - The Medical Letter and the Yale School of Medicine continuing medical education program. Exam No. 37.

Aug 1999 - The Medical Letter and the Yale School of Medicine continuing medical education program. Exam No. 38.

Feb 2000 - The Medical Letter and the Yale School of Medicine continuing medical education program. Exam No. 39.

Mar 2000 - "New pharmacologic options for the management of neuropathic pain: a practical treatment guide. Dannemiller Memorial Educational Foundation.

Apr 2000 - "Gullian-Barre Syndrome." American Association of Electrodiagnostic Medicine. Case Report #4.

Jun 2000 - "Costoclavicular Mass Syndrome." American Association of Electrodiagnostic Medicine. Case Report # 33.

Jan 2001 - "Electrodiagnostic Studies in Amyothrophic Lateral Sclerosis and Other Motor Neuron Disorders." American Association of Electrodiagnostic Medicine. Mimimonograph #18.

- "Botulism." American Association of Electrodiagnostic Medicine. Case Report #16.

May 2001 - "Assessment test." Rehab in Review.

CONTINUING MEDICAL EDUCATION – WRITTEN MATERIAL (Continued)

Oct 2001 - "Rehab in review assessment test." Spaulding Rehabilitation Hospital.

Nov 2001 - "Lawful prescribing and prevention of diversion." CME/CE Teleconference Series.

- "Rehab in review assessment test." Spaulding Rehabilitation Hospital.

Dec 2001 - "Rehab in review assessment test." Spaulding Rehabilitation Hospital.

Jan 2002 - The Medical Letter and the Yale School of Medicine continuing medical education program. Exam No. 43.

- "Advances in migraine prophylaxis program: Current state of the art and

future prospects." Finch University of Health Sciences/The Chicago Medical School

Jun 2002 - "Rehab in review assessment test." Spaulding Rehabilitation Hospital.

Oct 2002 - "Rehab in review assessment test." Spaulding Rehabilitation Hospital.

Dec 2002 - Contemporary Spine Surgery Volume 3 Issue 4. Lippincott Williams & Wilkins.

- The Medical Letter and the Yale School of Medicine Continuing Medical Education Program. Exam No. 45.

Feb 2003 - Contemporary Spine Surgery Volume 3 Issue 3. Lippincott Williams &Wilkins.

Mar 2003 - "Urine Drug Testing in Primary Care." 2002-2003 Monograph. California Academy of Family Physicians.

- "2001 AAEM Training Program Self-Assessment Examination Review Session." American Association of Electrodiagnostic Medicine

- "2001 AAEM Training Program Self-Assessment Examination." American Association of Electrodiagnostic Medicine.

Apr 2003 - "New analgesic options: Overcoming obstacles to pain relief." University of Wisconsin, Continuing Medical Education.

Feb 2005 - The Medical Letter and the Yale School of Medicine Continuing Medical Education Program. Exam No. 49.

Jan 2008 - "Neuroimaging: Interpreting Addiction." Emerging Solutions in Pain. David Schyler, PhD. Medicom.

VI. Study Roster

This is a list of additional personnel (IRB-approved) who will be involved in the study (and who are not listed on the title page).

Location 1:
Feinberg School of Medicine
Northwestern University
Dept of Physiology
Tarry Bldg 7th floor, 310 E Superior St.
Chicago, IL 60611

Etienne Vachon-Presseau, PhD
Postdoc – Data Analysis and Study Support
etienne.vachon.presseau@gmail.com
312-503-3039
Office 7-701
***works remotely most of time (email is best source of contact)

Melissa Farmer, PhD
Research Associate – Administrative Support
melissa-farmer@northwestern.edu
312-503-2562
Office 7-707

Alexis (Alex) Baria, PhD
Lab Manager – Scanning and Analytical Support
axlebaria@gmail.com
Office 7-665 (Morton corridor)
312-503-3971

Mariam Ghantous, MD
Postdoc – Scanning and Study Support
Office 7-751
312-503-1319

Rami Jabakhanji, PhD
Research Associate – Scanning and Study Support
Office 7-701
312-503-3039

Maria Virginia (Marivi) Centeno, MS
Technician – Technical Support and Database Quality Control
marivicenteno@gmail.com
312-503-1703
Office 7-767

Lejian Huang, PhD
Research Associate – Data Quality Control and Preprocessing
lejian@gmail.com
312-503-3195
Office 7-763

Beth Hunt, MA
Research Coordinator and Recruiter (also aids in administrative duties)
beth.hunt@northwestern.edu
312-503-6475
Office 7-701

Taha Abdullah, MS
Research Coordinator/Study Leader
taha.b.abdullah@gmail.com
312-503-0413
Office 7-731

Binbin Wu, MD
Visiting Scholar – Study support
Office 7-731
312-503-0413

Diane Reckziegel, PhD
Postdoc – Scanning and Study Support
312-503-3971
Office 7-705

Location 2:
Northwestern University Clinical and Translational Sciences Institute (NUCATS)
750 North Lake Shore Drive
Floor 11
Chicago, IL 60611

Priya Rakesh Tripathi
Regulatory Coordinator – Regulatory support and recruitment
priya.tripathi@northwestern.edu
312-503-4122

Ashley Sipocz
Research Project Coordinator – Regulatory support and recruitment
ashley.sipocz@northwestern.edu
312-503-2289 (desk #)
312-503-1709 (recruitment hotline #)

Annette Kinsella, RN, CCR
Clinical Research Nurse/Staff Educator/Trainer – bottling and blinding study agent
a-kinsella@northwestern.edu
312-503-2317

Location 3
Northwestern Memorial Hospital – Feinberg Pavilion
Research Pharmacy
251 E. Huron St.
LC-700
Chicago, IL 60611

Jane Regalado, Pharm D
Investigational Pharmacist – orders and encapsulates study agent
jregalad@nmh.org
312-926-7470

Location 4
Northwestern Memorial Hospital - Arkes Family Pavilion
676 North St. Clair St.
Diagnostic Testing Center (DTC)
Suite 280
Chicago, IL 60611

This center provides labs and phlebotomy services on an out-patient basis. This location is listed as a back-up in case the study staff is unable to draw blood at the first visit. Staff will fill out necessary form prior to escorting participant to this location and wait with them until their labs are taken.

Location 5
Northwestern University, Feinberg School of Medicine
Department of Physical Medicine & Rehabilitation,
10th floor Abbot Hall, 710 N Lake Shore Dr
Chicago, IL 60611

Julia Marks,
Clinical Research Manager, Study Support and Phlebotomy
julia.marks@northwestern.edu
312-503-1215

Narina Simonian, BS, CCRC – Study Support and Phlebotomy
Clinical Research Project Manager
n-simonian@northwestern.edu
312-503-5780

Amy Lange, R.N. – Study Support and Phlebotomy
Research Coordinator
amy.lange@northwestern.edu
312-503-9915

Katie Rankin, B.S. – Study Support and Phlebotomy
Project Coordinator
katie.rankin@northwestern.edu
312-503-4043

VII. Schedule of Evaluations and Assessments

Before Study Begins (visit/week not applicable):
Purpose: Set up all parameters necessary for the study to run smoothly

List of Items to be Completed:

- After approval from study sponsor, submit updated protocol and documentation to the Northwestern IRB for approval
- Order encapsulated study drugs (placebo, naproxen, and omeprazole)
- Order, bottle, and label rescue medication (acetaminophen)
- Pharmacy will randomize drugs according to our block design (sect 4.3)
- Create and organize participant folders
- Begin recruitment and pre-screen interested for initial eligibility (sects 2.1 and 2.2)

Visit 1: Consent and Baseline Pain Monitoring (week -3):
Purpose: Determine initial eligibility and collect the first of a subset of pre-treatment measurements; monitor baseline pain ratings without study interference

List of Items to be Completed:

- Informed consent – read and discuss, signature obtained
- Medical/pain history recorded
- Patient demographics recorded
- Physical exam and Vitals: temperature, pulse, respiration, blood pressure, weight, height
- Blood and urine collection: complete blood count, comprehensive chemistry panel including liver functions, pregnancy test (if applicable)
- Review eligibility criteria
- Review previous and current concomitant medications and side effects, if any, associated with them
- Assess initial pain intensity
- Begin washout of current pain medications
- Complete questionnaires***

- Dispense rescue medication

Interim 1: Monitor App Use
Collect daily pain and mood ratings on the electronic phone/computer app; monitor for eligible pain range (see Visit 2, bullet point 1)

Visit 2: Baseline Pre-Treatment Scan 1 (week -1):
Purpose: Collect the screening and safety measurements, complete the first scanning session, and continue to monitor pain ratings

List of Items to be Completed:

- Review interim VAS ratings for eligibility (≥ 5/10 pain on average over the 2 week period in Interim 1)
- Collect current VAS pain intensity
- Ask about any changes in clinical status since last visit
- Complete scanning session: T1, Resting, DTI
- Complete questionnaires***
- Dispense rescue medication

Interim 2: Stratification
Purpose: Use predictive model to stratify into placebo responders versus non-responders

List of Items to be Completed:

- Pre-process imaging data
- Send data through the model and based on results, stratify into responders versus non-responders
- Send stratification result to the pharmacy so that they can randomize participant accordingly
- Continue to monitor daily pain and mood app ratings

Visit 3: Randomization and Treatment starts (week 0):
Purpose: Collect measurements and randomize; begin treatment (if applicable)

List of Items to be Completed:

- Collect current VAS pain intensity
- Collect adverse events/changes in health, if any
- Document use of rescue medication
- Dispense additional rescue medication if needed
- Vitals
- Complete questionnaires***
- If in treatment group, pharmacy will give participants their already randomized and blinded study medication and specific instructions for taking it; provide with additional rescue medication; if in no-treatment group, independent assessor will notify participant of this assignment

Interim 3: Monitor App Use and Agent Compliance
Purpose: Collect daily pain and mood ratings on the electronic phone/computer app; monitor study agent compliance and/or rescue medication use

Visit 4: Interim Monitoring Visit (week 3):
Purpose: Collect measurements and continue treatment, if applicable

List of Items to be Completed:

- This list is identical to that in Visit 3

Interim 4: Same as Interim 3

Visit 5: Post Treatment Scan (week 6)
Purpose: Collect measurements; complete second/last scanning protocol; begin study medication washout

- Collect current VAS pain intensity
- Collect adverse events, if any
- Collect rescue medication
- Complete T1, resting state, DTI, and pain rating scans
- Questionnaires ***
- Begin washout period and provide additional rescue medication

Interim 5: Same as Interim 1

Visit 6: Final Visit (week 9)
Purpose: Collect measurements; end washout; complete study

- Collect current VAS pain intensity
- Collect adverse events, if any
- Vitals
- Questionnaires ***
- Return of phone, if applicable

VIII. Biostatistician CV

Curriculum Vitae

Name James William Griffith

E-mail j-griffith@northwestern.edu jameswgriffith@gmail.com

License Clinical Psychology, State of Illinois, U.S.A. #071.007223

Citizenship United States of America

- **New Orleans VA Medical Center**

EDUCATION

- American Psychological Association (APA) accredited psychology Internship
- Research areas: Cognition and emotional, longitudinal assessment of PTSD symptoms in Operation Desert Storm Veterans
- **The State University of New York at Binghamton**
- Doctor of Philosophy in Clinical Psychology, January 2004, Minor in Statistics (APA Accredited)
- Master of Arts, Clinical Psychology, August 2001
- Research areas: Depression and memory processes, life-events and mental health, comorbidity, psychological assessment
- **Temple University**
- Bachelor of Arts, Psychology, Magna Cum Laude, January 1998

HONORS AND AWARDS RECEIVED

- Graduate student award for excellence in teaching
- Tuition Scholarship at State University of New York (4 years)
- Travel expense award for AABT awarded by the psychology department (3, approximately $125 each)
- Temple University's College of Arts and Sciences Dean's Scholar (Spring 1997)
- Dean's List (Spring 1995, Fall 1995, Spring 1996, Spring 1997)
- Member of Psi Chi (National Honors Society in Psychology)
- Member of Golden Key Honor's Society

RESEARCH EXPERIENCE

- **K.U.Leuven, Centre for Experimental Psychopathology, 25 October 2011-present**
- **Senior visiting fellow**

Conducted analyses of overgeneral memory, rumination and treatment outcome data

- **Northwestern University, Department of Medical Social Sciences, April 27th, 2009-present**
- **Research Assistant Professor**
- Oversaw taste, audition, and somatosensation teams for ~$25 million NIH Toolbox contract
- Assisted with consulting to the pharmaceutical industry

- **Center on Outcomes Research and Education, July 15th, 2008-April 24th, 2009**
- **Research Scientist**
- Oversaw taste, audition, and somatosensation teams for ~$25 million NIH Toolbox contract
- Provided statistical consultation at internal medicine club
- **Northwestern University, Department of Psychology, August 2003-July 2008**
- **Postdoctoral Fellow/Project Director**
- Oversaw a NIMH-funded, longitudinal multi-site study of risk for emotional disorders
- Trained and supervised interviewers on the Structured Clinical Interviewer for DSM-IV and Hammen's Life Stress Interview
- Oversaw staff of project coordinators, graduate students, independent-study students, work-study students, and volunteers
- Coordinated screening of 200-300 adolescents per year and subsequent recruitment into longitudinal phase (cross-site *N* = 627)
- Oversaw data processing and data analysis
- Programmed computerized cognitive experiments in MediaLab and DirectRT
- **New Orleans VA Medical Center, July 2002-July 2003**
- **Psychology Intern**
- Analysis of archival data of post-deployment psychopathology in ODS veterans
- Designing computerized Stroop experiments (using E-Prime) for use with veterans
- Attend research meetings and didactic seminars
- Reviewed manuscripts and grant applications for various faculty members interested in PTSD and information processing
- **Pepper Research Lab, September 1998-July 2002**
- **Graduate Student Staff Member**
- Designed and conducted experiments with human participants
- Supervised undergraduate research assistants
- Set up and maintained five-terminal local area network
- Conducted diagnostic interviews as part of NIMH B-Start grant awarded to Dr. Carolyn Pepper (advisor)
- Worked as paid research assistant on life events and mood disorder research (Summer 1998)
- **Temple University Social Phobia Program (the clinic is now called "Adult Anxiety Clinics at Temple"), February 1996-June 1998**
- **Research Assistant**
- Made conceptual contributions to several research studies on the treatment outcome and etiology of social phobia
- Interacted with research participants including college students and persons with psychiatric disabilities
- Created Microsoft Access databases for several NIMH-funded research studies
- Acted as liaison between lab and major computer vendor
- Upgraded and maintained computer hardware and software
- Maintained file backup system for lab computers

TEACHING EXPERIENCE

- **Center on Outcomes Research and Education, July 2008-April 2009**
- Developed logistic regression seminar for department of surgery
- **The State University of New York at Binghamton, September 1998-July 2002**
- **Course Instructor**
- Instructor of record for undergraduate Statistics and Design course
- Teaching assistant for graduate Statistics and Design I and II
- Instructor for General Psychology Laboratory
- Teaching assistant for undergraduate Statistics and Design

▪ CLINICAL AND COMMUNITY EXPERIENCE

- **The Family Institute, August 2003-present**
- **Affiliate Therapist**
- Conduct individual therapy with adults
- **New Orleans VA Medical Center, July 2002-July 2003**
- **Psychology Intern**
- Conducted individual and group therapy for women who report past sexual trauma
- Taught smoking cessation classes
- Conducted individual and group psychotherapy for veterans with PTSD
- Conducted compensation and pension evaluations
- **Syracuse VA Medical Center, September 2001-May 2002**
- **Psychology Trainee**
- Administered neuropsychological and psychological testing and psychotherapy in behavioral health and primary care settings
- Attended grand rounds and training seminars in topics such as PTSD and veteran culture
- Consulted with supervising psychologists about data analysis for staff morale project

Broome County Community Mental Health, September 1999-June 2000

Administrative Trainee

- Conducted and presented research on the functioning of Broome County's mental health system
- Provided consultation to Mental Health Commissioner regarding community research projects and interpretation of state, county, and agency mental health data
- Interviewed local mental health professionals and consumers pursuant to gathering data to inform county mental health expenditures, program planning, and program development
- Presented findings to Mental Health Commissioner's advisory subcommittee

- **The Psychological Clinic (Student Clinic at SUNY), 1999-May 2002**

- Administered neuropsychological and psychological testing and psychotherapy
- Cases included clients with major depressive disorder, generalized anxiety disorder, panic disorder, memory problems, and learning disabilities

▪ TRAINING WORKSHOPS ATTENDED

- 22 May 2008: Mixed Models for Longitudinal Data Analysis. Facilitated by Donald Hedeker.

▪ DEPARTMENTAL SERVICE

- 2010-2011: Search Committee for junior developmental neuroscientist

▪ PUBLICATIONS

Griffith, J. W., Kleim, B., Sumner, J. A., & Ehlers, A. (in press). The factor structure of the Autobiographical Memory Test in recent trauma survivors. *Psychological Assessment.*

Griffith, J. W. (in press). Exploratory Factor Analysis. Encyclopedia entry to be published in the *Encyclopedia of Quality of Life Research.*

Uliaszek, A. A., Zinbarg, R. E., Mineka, S., Craske, M. G., **Griffith, J. W.**, Sutton, J. M., Epstein, A., & Hammen, C. (in press). A longitudinal examination of stress generation in depressive and anxiety Disorders. *Journal of Abnormal Psychology.*

Barnhofer, T., Duggan, D., & **Griffith, J. W.** (in press). Dispositional mindfulness moderates the relation between neuroticism and depressive symptoms. Submitted to *Personality and Individual Differences.*

Hahn, E. A., Choi, S. W., **Griffith, J. W.**, Yost, K. J., & Baker, D. B. (2011). Health Literacy Assessment Using Talking Touchscreen Technology (Health LiTT): A New Item Response Theory-based Measure of Health Literacy. *Journal of Health Communication, 16,* 150-162. doi: 10.1080/10810730.2011.605434

Prenoveau, J. M., Craske, M. G., Zinbarg, R. E., Mineka, S., Rose, R. D., & **Griffith, J. W.** (in press). Are anxiety and depression just as stable as personality during late adolescence? Results from a three-year longitudinal latent variable study. *Journal of Abnormal Psychology.*

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Prenoveau, J. M., Zinbarg, R. E., Craske, M. G., Mineka, S., **Griffith, J. W.**, & Rose, R. D. (2009). Evaluating the Invariance and Validity of the Structure of Dysfunctional Attitudes in an Adolescent Population. *Assessment, 16,* 258-273.

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Zinbarg, R. E., & **Griffith, J. W.** (2008). Behavior therapy. In J. L. Lebow (Ed.). *Twenty First Century Psychotherapies*. Hoboken, NJ: John Wiley & Sons.

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Jeglic, E. L., Pepper, C. M., Ryabchenko, R. A., **Griffith, J. W.**, Millller, A. B. & Johnson, M. (2005). Coping with a partner's depression: A caregiving model. *Family Relations, 54,* 37-45.

Ryabchenko, K. A., Pepper, C. M., Jeglic E. L., **Griffith, J. W.,** & Miller, A. B. (2004). Differences in course and comorbidity of recurrent depression in primary care and psychiatric populations. *Depression and Anxiety, 20,* 153-154.

Griffith, J. W. (2003) The Cochran's Q. In M. Lewis-Beck, A. E. Bryman, & T. F. Liao (Eds.). *Sage Encyclopedia of Social Science Research Methods*. Sage Publications: Thousand Oaks, CA.

Griffith, J. W. (2001). Professionals' beliefs regarding child sexual abuse: Assessment and treatment implications. *The Journal of Threat Assessment, 1,* 35-61.

▪ MANUSCRIPTS SUBMITTED FOR PUBLICATION

Uliaszek, A. A., Zinbarg, R. E., Mineka, S., Craske, M. G., Sutton, J. M., **Griffith, J. W.**, Rose, R., Waters, A., & Hammen, C. The Role of Personality in the Stress-Depression and Stress-Anxiety Relationships. Submitted to *Personality and Individual Differences*.

Schoofs, H., Raes, F., Griffith, J. W., & Hermans, D. (2011). Rumination Relates to Reduced Autobiographical Memory Specificity in Formerly Depressed Patients Following a Self-Discrepancy Challenge: The Case of Autobiographical Memory Specificity Reactivity. Submitted to *Behavior Research and Therapy.*

▪ MANUSCRIPTS UNDER REVISION

Griffith, J. W., Zinbarg, R. E., Mineka, S., Sutton, J. & Craske, M. G. Association of neuroticism and cognitive vulnerability for depression.

Griffith, J. W. Warrier, C., Zecker, S. Siegle, J. H, & Dhar, S. An item response theory analysis of the Hearing Handicap Inventory.

Griffith, J. W., Constans, J. I., Brailey, K., & Vasterling, J. J. Cognitive bias in posttraumatic stress disorder (PTSD): Impact of a trauma-related stressor on the emotional Stroop task.

▪ MANUSCRIPTS IN PREPARATION

Salsman, J. M., Butt, Z., Pilkonis, P. A., Cyranowski, J. M., Zill, N., Hendrie, H. C., Kupst, M. J., Kelly, M. A. R., Bode, R. K., Choi, S. W., Lai, J-S., **Griffith, J. W.**, & Cella, D. Emotional Health and its Assessment within the NIH Toolbox. To be submitted to *Neurology* for inclusion in a special issue.

Coldwell, S. E., Mennella, J. A., Duffy, V. B., Pelchat, M. L., **Griffith, J. W.**, Smutzer, G., Cowart, B. J., Breslin, P. A. S., Bartoshuk, L. M., Hastings, L., Beauchamp, G. K., O'Mahony, M. A., Victorson, D., & Hoffman,

H. (2010). NIH Toolbox for Neurological and Behavioral Function: Assessments for gustation. To be submitted to *Neurology* for inclusion in a special issue.

Griffith, J. W., Pepper, C. M., Ryabchencko, K. & Calabrese V. Reality monitoring and depressive disorders.

Doane, L.D., Adam, E.K., Mineka, S., Zinbarg, R., **Griffith, J. W.**, & Craske, M. Flattened diurnal cortisol rhythms as a scar marker of past depressive episodes and a state marker of current negative emotion in a community sample of adolescents.

▪ GRANTS FUNDED

- NorthShore University HealthSystem CCRP Grant
  - Topic: Development and IRT analysis of a dysmenorrhea self-report instrument
  - Total grant = $60,000, direct salary support = $5,000
  - Role: Co-principal investigator

▪ GRANT APPLICATIONS

- NorthShore pilot grant (2008, Not Funded)
- CORE Davis Award (2008, Not Funded)
- NIH Extramural Loan Repayment Program (2004, Not Funded)
- Individual National Research Service Award #1-F31-MH65753-01. *Reality Monitoring and Major Depression* (2001, Not Funded)
- Society for a Science of Clinical Psychology Dissertation Grant. *Reality Monitoring and Major Depression* (2001 & 2002, Not Funded)

▪ EDITORIAL EXPERIENCE

- Ad-hoc reviewer for *Clinical Psychology Review* (1)
- Ad-hoc reviewer for *Journal of Psychopathology and Behavioral Assessment* (1)
- Reviewer for *Behaviour Research & Therapy* (31)
- Reviewer for *Journal of Abnormal Psychology* (10)
- Reviewer for *Emotion* (1)
- Reviewer for *International Journal of Methods in Psychiatric Research* (1)
- Reviewer for *Journal of Affective Disorders* (1)
- Reviewer for *British Journal of Clinical Psychology* (2)
- Reviewer for *Cognition and Emotion* (1)
- Reviewer for *Journal of Behaviour Therapy and Experimental Psychiatry* (1)
- Reviewer for *Brain, Behavior, and Immunity* (2)
- Reviewer for Biomed Central Psychiatry (1)
- Reviewer for *Journal of Traumatic Stress (1)*
- Reviewer for *American Journal of Psychology* (1)
- Reviewer for *Neuropsychologia* (1)
- Reviewer for *Social Science Research* (1)
- Reviewer for *Cognitive Therapy and Research* (1)

- British Psychology Society

▪ PROFESSIONAL MEMBERSHIPS

- American Psychological Association
- American Psychological Association Practice Organization
- Association for the Advancement of Behavior and Cognitive Therapies

▪ COLLOQUIA and INVITED PRESENTATIONS

- NorthShore University HealthSystem psychiatry grand rounds. *The Youth Emotion Project: Assessing risk for anxiety and depression* (January, 20th, 2009).

- Katholieke Universiteit Leuven (in English – The University of Leuven, Belgium). *The Youth Emotion Project: Assessing risk for anxiety and depression* (February 2008)
- University of Zürich *The Youth Emotion Project: Associations among Neuroticism, Psychopathology, and Cognitive Vulnerability for Depression.* (11 November 2010)
- Annual Meeting of the International Pelvic Pain Society. *MAPP – Project II, Northwestern University: Self-report assessment of UCPPS.* (22 October 2011, Las Vegas, Nevada)

▪ OTHER PRESENTATIONS

- Future Directions in Cognition and Emotion Research (CORE Internal Seminar, October 2008)
- The Youth Emotion Project: Assessing Autobiographical Memory (Job talk to CORE, June 2008)
- All Good Things Must End… (Case conference given to VAMC MH and PTSD staff, May 2003)
- Why Worry? The case of "Fred" (Assessment case conference given to VAMC MH and PTSD staff, December 2002)
- Cleaning Up Your Data with SPSS(given to VAMC research staff, October 2002)
- Case Conference: Sixty years of PTSD (February 2002)
- Case Conference: Community Mental Health Services: A Needs Assessment (with R. Russell & A. Johnson)
- Evaluating Mental Health Services in Broome County (given to Broome County MH subcommittee)
- Evaluating Case Management and Residential Services In Broome County (given to Broome County MH subcommittee)
- Computerized data analysis with SPSS (given to first-year graduate statistics class)

▪ CONFERENCE PRESENTATIONS

Barkema, D., Linn, S. Ruppert, L., Wysocki1, N. Streff, L., Bhuva, S. Welbel, R. Gordon, K., **Griffith, J.** Samuels, D. & Schnitzer, T. (2011). Heel Ultrasound compared to DXA in Spinal Cord Injury. Poster to be presented at the American Society for Bone and Mineral Research. San Diego, CA, U.S.A.

Desai, H., Coldwell, S. E., **Griffith, J. W.**, Hastings, L., & Smutzer, G. S. (2011). Validation of commercial PROP taste strips for the NIH Toolbox. Poster presented at the annual meeting of the Association for Chemoreception Sciences.

Polster, R., **Griffith, J. W.**, Calhoun, E. A., Tu, F. F., Cella, D., & Gershon, R. (2010). Patient-Reported Measurement Aspects of Chronic Pelvic Pain: MAPP Northwestern University Project II Preliminary Results from Qualitative Interviews with Pelvic Pain Patients. Poster presented at the annual meeting of the International Pelvic Pain Society.

Hahn, E. A., Choi, S. W., **Griffith, J. W.**, Yost, K. J., & Baker, D. W. (2010). A New Multimedia Health Literacy Item Bank Developed Using Item Response Theory. Poster to be presented at the 2nd annual meeting of the *Health Literacy Annual Research Conference,* Boston, MA, U.S.A.

Coldwell, S., **Griffith, J. W.**, & Victorson, D. (2009). Initial selection of taste perception assessment measures for NIH Toolbox, Poster to be presented at the 21st annual meeting of the Association for Psychological Science, San Francisco, U.S.A.

Sumner, J.A., Mineka, S., **Griffith, J. W.**, Zinbarg, R., & Craske, M. (2008, May). Overgeneral autobiographical memory predicts unipolar mood disorders in adolescents. Poster presentation at the 20th annual meeting of the Association for Psychological Science, Chicago, IL.

Bostick, S., Epstein, A., Dickson, D., Craske, M. G., Mineka, S., Zinbarg, R. E., & **Griffith, J. W.** (2008). Anxiety and depression: Potential mediators between stressful life events and alcohol use disorders at one year follow up. *Abstract submitted to* the 42nd meeting of the *Association for Behavioral and Cognitive Therapies*, Orlando, FL.

Sumner, J., Mineka, S., **Griffith, J. W.**, Zinbarg, R., & Craske, M. (2007, October). Autobiographical memory specificity as a predictor of unipolar mood disorders in adolescents. Poster presentation at the 21st annual meeting of the Society for Research in Psychopathology, Iowa City, IA.

Yeh, M. V., **Griffith, J. W.**, Mineka, S., & Zinbarg, R. E. (2007). Neuroticism and anxiety sensitivity: Predicting anxious and depressive symptoms. Poster presented at the 41st meeting of the *Association for Behavioral and Cognitive Therapies*, Philadelphia, PA.

Zinbarg, R. E., Craske, M. G., Mineka, S., & **Griffith, J. W.** & Rose, R. D. (2007). Personality, Cognitive Style and Diagnoses in Adolescents: Cross-sectional and Prospective Prediction of Emotional Disorders. Symposium talk presented at the 41st meeting of the *Association for Behavioral and Cognitive Therapies*, Philadelphia, PA.

Griffith, J. W., Mineka, S. Craske, M. G., Zinbarg, R. E., Sumner, J. A. Lewis, A. R., Rekart, K. (2007). Cognitive Predictors of Depression. Symposium talk presented at the 41st meeting of the *Association for Behavioral and Cognitive Therapies*, Philadelphia, PA.

Epstein, A. Craske, M G., Shoptaw, S., Stein, J. Mineka, S., Zinbarg, R. E., **Griffith, J. W.**, & Rose, R. D. (2007). A Prospective Examination of Risk Factors for Alcohol Use Disorders in Adolescents. Symposium talk presented at the 41st meeting of the *Association for Behavioral and Cognitive Therapies*, Philadelphia, PA.

Epstein, A. M., Dickson, D., Castriotta, N., Craske, M.G., Mineka, S., Zinbarg, R. E., & **Griffith, J. W.** (2007).
Risk Factors Predicting Lifetime and Future Alcohol Use Disorders in Male and Female Adolescents. Poster presented at the 30th annual meeting of the *Research Society on Alcoholism*, Chicago, IL.

Adam, E. K., Doane, L. D., Medelsohn, K., **Griffith, J. W.**, Mineka, S., Zinbarg, R. E., & Craske, M. G. (2007). Diurnal cortisol patterns, stressful life events, momentary negative emotion and mood and anxiety disorders in late adolescence. Paper to be presented at the *Society for Research in Child Development*.

Sutton J, Mineka S, **Griffith J. W.**, Zinbarg R, & Craske M. (2006). Prospective relationships between neuroticism, cognitive styles, and life stress with depressive and anxious symptoms. Poster presented at the *Association for Psychological Science*, 18th Annual Meeting, New York, NY.

Sutton J, Mineka S, **Griffith J**. **W.**, Zinbarg R, Craske M, & Rose, R. Neuroticism, cognitive vulnerabilities, and life stress: Concurrent relationships with depressive and anxious symptoms. (2006). Poster presented at the *Society for Research in Psychopathology*, 20th Annual Meeting, San Diego, CA.

Haller, M., Sutton, J., Mineka, S., Zinbarg, R., Craske, M., & **Griffith, J. W.** (2006). The impact of chronic and episodic stress on personality and attributional style. Poster presented at the *Associations for Behavioral and Cognitive Therapies*, 40th Annual meeting, Chicago, IL.

Oehlberg, K., Mineka, S., **Griffith, J. W.,** Zinbarg, R. E., & Craske, M. G. (2006). Social Phobia and Emotional Stroop Bias: Predictive Value of Attentional Interference. Poster presented at the Society for Research in Psychopathology.

Hauner, K. K. Y., Adam, E. K., Mineka, S., Doane, L. D., Zinbarg, R. E., Craske, M. G., & **Griffith, J. W.** (2006, May). Personality as a predictor of salivary cortisol patterns in adolescents. Poster presented at the 18th Annual Convention for the Association of Psychological Science, New York, NY.

Callahan, C., Rose, R. D., Nazarian, M., **Griffith, J. W.**, Zinbarg, R. E., Mineka, S., & Craske, M. G. (2005). Ethnic and gender differences among adolescents' cognitive styles. Poster presented at the 39th annual meeting of The Association for the Advancement of Behavior Therapy, Washington, D.C.

Spies, L. A., **Griffith, J. W.**, Mineka, S., Zinbarg, R. E., & Craske, M. (2005). Sociotropy, Autonomy, and their Relationship to Emotional Disorders in Adolescence. Poster presented at the 39th annual meeting of The Association for the Advancement of Behavior Therapy, Washington, D.C.

Doane, L., Adam, E., Mineka, S., Zinbarg, R. E., Craske, M., **Griffith, J.W.**, & Rose, R. (2005). *Longitudinal associations among emotion, stress, and cortisol on the emergence of depressive and anxious disorders.* Symposium talk presented at the Society for Research in Adolescence.

Griffith, J. W., & Constans, J. I. (2004). *Suppression of the Subliminal Stroop Effect in Vietnam Veterans with PTSD*. Poster presented at the 38th annual meeting of The Association for the Advancement of Behavior Therapy, New Orleans, LA.

Chiong, A., **Griffith, J. W.**, Mineka, S., Zinbarg, R. E., & Craske, M. G. (2004). *Differences Between Subliminal and Supraliminal Stroop in Adolescents at High Risk for Emotional Disorders*. Poster presented at the 38th annual meeting of The Association for the Advancement of Behavior Therapy, New Orleans, LA.

Zinbarg, R. E., Craske, M. G., Rose, R., **Griffith, J. W.**, Waters, A., Mineka, S., & Mor, N. (2004). *Lifetime and Current Diagnoses and Validity of Peer Reports of Personality and Attributional Style in Adolescents*. Symposium talk presented at the 38th annual meeting of The Association for the Advancement of Behavior Therapy, New Orleans, LA.

Mineka, S., Craske, M. G., Zinbarg, R. E., Mor, N., Rose, R., & **Griffith, J. W.** (2004). *Comorbidity of Anxiety and Mood Disorder in a High Risk Sample of Adolescents*. Symposium talk presented at the 38th annual meeting of The Association for the Advancement of Behavior Therapy, New Orleans, LA.

Griffith, J. W., Mineka, S., Newcomb-Rekart, K., Zinbarg, R. E., & Craske, M. G. (2004). *Information- processing Biases and Neuroticism as Predictors of Anxiety and Depression in Adolescents*. Symposium talk presented at the 38th annual meeting of The Association for the Advancement of Behavior Therapy, New Orleans, LA.

Griffith, J. W., Pepper, C. M., Ryabchenko, K., A., Calabrese, V., Miller, A. B., & Jeglic, E. L. (2004). *Reality Monitoring and Major Depression*. Poster presented at the 19th annual meeting of the Society for Research in Psychopathology, St. Louis, MO.

Mineka, S. Craske, M., Zinbarg, R. E., **Griffith, J. W.**, & Rose, R. (2004). *Neuroticism, extraversion and the lifetime prevalence of emotional disorders in adolescents*. Poster presented at the 19th annual meeting of the Society for Research in Psychopathology, St. Louis, MO.

Sutton, J. M., Mineka, S., Mor, N., **Griffith, J. W.**, & Zinbarg, R. E. (2004) *The Specificity of Cognitive, Personality, and Life Stress Variables to Depressive and Anxious Symptoms.* Poster presented at the 19th annual meeting of the Society for Research in Psychopathology, St. Louis, MO.

Sutton, J. M., Mineka, S., Mor, N., **Griffith, J. W.**, Jaeger, J., & Zinbarg, R. E. (2004). *The Relationship of Cognitive Styles, Personality, and Life Stress to Depressive Symptoms*. Poster presented at the 16th meeting of the American Psychological Society, Chicago, IL.

Griffith, J. W., Vasterling, J., Brailey, K., Constans, J. I., & Sutker, P. B. (2003). *Depression and PTSD over time in 1991 Gulf War veterans: The effect of stress and coping.* Symposium presentation at the meeting of the International Society for Traumatic Stress Studies, Chicago, IL.

Griffith, J.W., Fassler, O., Sonin, K., Dudas, M., & Pepper, C.M. (2002). *Can retrieval cues decrease the depressive memory bias?* Poster presented at the meeting of the Eastern Psychological Association, Boston, MA.

Griffith, J.W., Jeglic, E., Miller, A., Ryabchenko, K.A., & Pepper, C.M. (2001). *Symptom Reduction Following The SCID-IV In A Primary Care Sample*. Poster presented at the 35th annual convention of the Association for the Advancement of Behavior Therapy, Philadelphia, PA.

Griffith, J.W., Miller, A., & Pepper, C.M. (2001). *A Comparative Examination of the Validity of Mailback Follow-Up Assessments*. Poster presented at the 35th annual convention of the Association for the Advancement of Behavior Therapy, Philadelphia, PA.

Griffith, J.W., Dudas, M., Fassler, O., Flora, R., & Pepper, C.M. (2001). *Depressive Memory Bias: Verbatim Or Gist Based?* Poster presented at the 35th annual convention of the Association for the Advancement of Behavior Therapy, Philadelphia, PA.

Jeglic, E.L., Ryabchenko, K.A., Miller, A.B., Vanderhoff, H.A., **Griffith, J.W.**, & Pepper, C.M. (2001). *Spousal perceptions of depressive symptomatology*. Poster presented at the 35th annual convention of the Association for the Advancement of Behavior Therapy, Philadelphia, PA.

Jeglic, E.L., Ryabchenko, K.A., Miller, A.B., Vanderhoff, H.A., **Griffith, J.W.**, & Pepper, C.M. (2001). *A caregiving model of depression*. Poster presented at the 35th annual convention of the Association for the Advancement of Behavior Therapy, Philadelphia, PA.

Ryabchenko, K.A., Jeglic, E., **Griffith, J.W.**, Miller, A., Axelrad M., & Pepper, C.M. (2001). *Recurrence of Major Depression In A Primary Medical Care And An Outpatient Psychiatry Sample*. Poster presented at the 35th annual convention of the Association for the Advancement of Behavior Therapy, Philadelphia, PA.

Pepper, C. M., Ryabchenko, K. A., Jeglic, E. L., **Griffith, J. W.** and Miller, A. B. (2001, November). *Course and comorbidity of recurrent depression in two treatment settings*. Poster presented at the annual meeting of the Society for Research in Psychopathology, Madison, WI.

Griffith, J.W., Jeglic, E., Ryabchenko, K.A., Lam, C.Y., & Pepper, C. (2000). *Comorbid Alcohol-Related Disorders And Major Depression In A Primary Care Sample.* Poster to be presented at the 34th annual convention of the Association for the Advancement of Behavior Therapy, New Orleans, Louisiana.

Griffith, J.W., Ryabchenko, K.A., Lam, C., Jeglic, E., & Pepper, C. (2000) *Psychiatric Comorbidity in a College Sample*. Poster to be presented at the 34th annual convention of the Association for the Advancement of Behavior Therapy, New Orleans, Louisiana.

Miller, A., Williams, K., Pepper, C., Vetrano, M., Idoniboye, L., Dossa, F., Jeglic, E., Ryabchenko, K., **Griffith, J.W.**, & Axelrad, M. (2000). *Rates of depression and head injury in patients with chronic hepatitis*

Poster to be presented to the 34th annual convention of the Association for the Advancement of Behavior Therapy, New Orleans, Louisiana.

Ryabchenko, K.A., Jeglic, E., **Griffith, J.W.**, Lam, C., Pepper, C.M. (November 1999). *Identifying Predictors of Major Depression in a Primary Care Population (II)*. Poster presented at the 2000 annual meeting of the American Psychosomatic Society. Savannah, Georgia.

Griffith, J.W., Ryabchenko, K.A., Lam, C., Jeglic, E., & Pepper, C.M. (November 1999). *A Two-stage Screening for Major Depression in a College Sample.* Poster presented at the 33rd annual convention of the Association for the Advancement of Behavior Therapy, Toronto, Canada.

Ryabchenko, K.A., Jeglic, E., **Griffith, J.W.**, Lam, C., Pepper, C.M. (November 1999). *Identifying Predictors of Major Depression in a Primary Care Population (I)*. Poster presented at the 33rd annual convention of the Association for the Advancement of Behavior Therapy, Toronto, Canada.

VIII. Laboratory Procedures/Evaluations

Clinical Laboratory Evaluations

Baseline laboratory values will be collected for determination of inclusion/exclusion criteria and to assess safety and also will be entered into the study database. Repeat laboratory testing will only be done if there is a clinical basis for further testing. Blood and urine samples will be collected at the MRI scanning facility by a RN or trained member of the research personnel. If for some reason a blood pregnancy test cannot be obtained, urine pregnancy tests will be processed at the MRI scanning facility before starting any procedures, including scanning. Blood samples will be processed through Pathology Laboratory at NMH, 251 E. Huron St. LC700, Chicago, IL 60611. All results will be faxed to the study doctor for review before subjects begin study medications. Samples will not be frozen nor stored for long-term or future use. All results will be entered into REDcap after the study physician has looked over them and noted out of range results and plan of action, if necessary.

Screening Laboratory Evaluations

- The normal ranges for each test is listed within the brackets below.

Hematology - Complete Blood Count (CBC)

9 tests will be performed. Normal results will be required before starting all study medications.

- White cell count [3.5-10.5 K/UL, normal reference range]
- Red cell count [3.80-5.20 M/UL]
- Hemoglobin [11.6-15.4 g/dL]

- Hematocrit HCT [34.0-45.0%]
- MCV [80-99 FL]
- MCH [27.0-34.0 pg]
- MCHC [32.0-35.5%]
- RDW [11.0-15.0%]
- Platelet count [140-390 K/UL]

Hematology - Differential

10 tests will be performed. Normal results will be required before starting all study medications.

- Neutrophils [34-73%]
- Lymphocytes [15-50%]
- Monocytes [5-15%]
- Eosinophils [0-8%]
- Basophils [0-2%]
- Absolute neutrophils [1.5-8.0 K/UL]
- Absolute lymphocytes [1.0-4.0 K/UL]
- Absolute monocytes [0.2-1.0 K/UL]
- Absolute eosinophils [0.0-0.6 K/UL]
- Absolute basophils [0.0-0.3 K/UL]

Comprehensive Chemistry Panel

16 tests will be performed. Normal results will be required before starting all study medications.

- Sodium [134-142 mEq/L]
- Potassium [3.5-5.1 mEq/L]
- Chloride [98-109 mEq/L]
- Bicarbonate [21-31 mEq/L]

- Blood urea nitrogen [2-25 mg/dL]
- Creatinine [0.00-1.30 mg/dL]
- eGFR – African Am [>=60 mL/min/1.73m2]
- eGFR – Non African Am [>=60 mL/min/1.73m2]
- Glucose level [65-100 mg/dL]
- Calcium [8.3-10.5 mg/dL]
- Albumin [3.5-5.7 g/dL]
- Total protein [6.4-8.9 g/dL]
- ALT [0-52 Unit/L]
- AST [0-39 Unit/L]
- Total bilirubin [0.0-1.0 mg/dL]
- Alkaline phosphatase [34-104 Unit/L]
- BAC [negative result needed]; looks for levels of ethyl glucuronide and ethyl sulfate

Vital signs

- Blood Pressure – diastolic [60-90 mm Hg]
- Blood Pressure – systolic [100-130 mm Hg]
- Pulse [60-100 beats/minute]
- Respirations [10-16 breaths/minute]
- Temperature [36-37.5^{o}C]

Urine Tests

A pregnancy test will be performed on all WOCBP prior to starting treatment, via either blood or urine. A negative test result will be required before receiving study medication and before starting scanning procedures.

Special Assays or Procedures

N/A

Specimen Preparation, Handling, and Storage

N/A

Specimen Shipment

N/A

Clinical Laboratory Evaluations

Baseline laboratory values will be collected for determination of inclusion/exclusion criteria and to assess safety and also will be entered into the study database. Repeat laboratory testing will only be done if there is a clinical basis for further testing. Blood and urine samples will be collected at the MRI scanning facility by a RN or trained staff member. Urine pregnancy tests will be processed before starting any study medication and before any scan is done. Blood and urine samples will be processed through Pathology Laboratory at NMH, 251 E. Huron St. (7th floor), Chicago, IL 60611; samples will be taken immediately to laboratory window after collection. All results will be faxed to the study doctor for review before participants begin study medications. Samples will not be frozen nor stored for long-term or future use.

In the rare cases that a participant cannot a provide blood or urine sample at the time of the visit *OR* if the RN or staff member cannot draw blood due to difficult veins, the following will be done. For individuals who cannot provide a sample the same day as visit 1, they will be rescheduled within 5 days for a blood draw/urine collection with the hospital diagnostic testing center (DTC, listed in the appendix locations); a member of the study staff will escort them to the center and wait with them until the samples have been collected. Participants will be reimbursed for travel up to $20 for this extra visit if needed. For individuals with difficult veins, study staff will escort them to the DTC at the end of the visit and wait with them until the samples have been collected.