

The Role of Disease Duration and Pain Catastrophizing in Patients with Chronic
Nonspecific Low Back Pain

By Theodora Costin

APPROVED:

Ladislav Dory PhD, Major Professor

Harlan Jones PhD, Committee Member

Ms. Cathleen Kearns, Committee Member

Stephen Mathew PhD, Clinical Research Management Graduate Advisor

Dean, Graduate School of Biomedical Sciences

The Role of Disease Duration and Pain Catastrophizing in Patients with Chronic Nonspecific Low Back Pain

Presented to the Graduate Council of the
Graduate School of Biomedical Sciences

University of North Texas

Health and Science Center

Fort Worth, Texas

In Partial Fulfillment for the Requirements for the Degree of Master of Science in Clinical Research Management

By Theodora Costin

November 2018

Acknowledgements

I would like to express my deepest appreciation to the committee members for their time and dedication to this project. First, I would like to thank my major professor, Dr. Ladislav Dory for his guidance and advice throughout this project as well as his commitment to my growth as a student. I would also like to thank Dr. Stephen Mathew and Dr. Harlan Jones for their efforts and input as committee members.

My biggest gratitude to Cathleen Kearns, my internship supervisor at the Osteopathic Research Center, for her support, valuable time, and dedication throughout my internship. She has provided me numerous, variable opportunities to expand my knowledge and skills in research that I am grateful for. Also, a big thank you to Samantha Johnson, Project Coordinator for the PRECISION TEXAS Pain Research Registry for taking time to train me for my position and for her guidance and wisdom throughout my internship experience. I would like to extend gratitude to Dr. John Licciardone, the principal investigator for PRECISION TEXAS, for his input and guidance in developing my research proposal, for allowing me to use his data to complete my research project, and for assistance with the statistical analysis portion of my project. As a non-committee member, his interest and effort in expanding my education in research has been a blessing.

Lastly, I would like to thank my family for continuous support throughout this Master program and my continuing education.

LIST OF ABBREVIATIONS

ACT: Acceptance and Commitment Therapy

CBT: Cognitive-Behavioral Therapy

HIPAA: Health Insurance Portability and Accountability Act of 1996

HS: Health Status

IPS: The Safety and Efficacy of Opioids in Patients with Low Back Pain: A Registry-Based Cohort Study to Compare Single- and Multi-Gene Approaches to Precision Medicine Prescribing vs. Usual Care

IRB: Institutional Review Board

LBP: Low Back Pain

NSAID: Non-steroid anti-inflammatory drug

ORC: Osteopathic Research Center

PCS: Pain Catastrophizing Scale

PRECISION TEXAS: Pain Registry for Epidemiological, Clinical, and Interventional Studies in North Texas

PTX: PRECISION TEXAS

QoF: Quality of Life

REDCap: Research Electronic Data Capture

VAS: Visual Analogue Scale

LIST OF TABLES

Table 1: Population Demographics.....	13
Table 2: Group Statistic for non-pharmacological treatments received.....	14
Table 3: Group Statistic for current medication use.....	15
Table 4: Group Statistics for Pain Catastrophizing Scores (Total).....	16
Table 5: Independent t-test results for Total PCS.....	16
Table 6a: Depression diagnosis Group Statistics.....	16
Table 6b: Mean scores of PROMIS-29 between groups.....	17
Table 7a: Partially-adjusted Multivariate Linear Regression for PCS.....	18
Table 7b: Fully-adjusted Multivariate Linear Regression for PCS.....	18
Table 8: Group statistics for Pain Catastrophizing Scores by Individual Dimension.....	20
Table 9: Independent t-test results for each PCS dimension.....	20
Table 10a: Fully-adjusted Multivariate Linear Regression for Rumination.....	21
Table 10b: Fully-adjusted Multivariate Linear Regression for Magnification.....	21
Table 10c: Fully-adjusted Multivariate Linear Regression for Helplessness.....	21
Table 11: PROMIS-29 Raw score conversion table.....	44

LIST OF FIGURES

Figure 1: Frequency of PCS for Rumination.....	40
Figure 2: Frequency of PCS for Magnification.....	41
Figure 3: Frequency of PCS for Helplessness.....	42

TABLE OF CONTENTS

List of Abbreviations.....	v
List of Tables.....	vi
List of Figures.....	vii

CHAPTERS

I.	INTRODUCTION.....	1
II.	RESEARCH PROJECT.....	3
	a. Background Information.....	3
	b. Specific Aims and Significance.....	8
	c. Experimental Design: Methods and Materials.....	9
	d. Results.....	12
	i. Aim 1.....	15
	ii. Aim 2.....	17
	iii. Aim 3.....	19
	e. Discussion and Concluding Thoughts.....	22
III.	INTERNSHIP EXPERIENCE.....	26
	a. Internship Site.....	26
	b. Internship Activity and Experience.....	28
IV.	REFERENCES.....	34
V.	APPENDICES.....	39
	a. APPENDIX A: Supplemental Data.....	39
	b. APPENDIX B: Questionnaires and Score Conversion.....	42

c. APPENDIX C: IRB Forms.....	44
d. APPENDIX D: Internship Journal Log.....	88

LIST OF APPENDICES

APPENDIX A: Supplemental Data

a. Figure 1: Frequency of PCS for Rumination.....	39
b. Figure 2: Frequency of PCS for Magnification.....	40
c. Figure 3: Frequency of PCS for Helplessness.....	41

APPENDIX B: Questionnaires and Score Conversion

a. Pain Catastrophizing Scale.....	42
b. PROMIS-29 Quality of Life Depression Questionnaire.....	43
c. Table 11: PROMIS-29 Raw score conversion table.....	43

APPENDIX C: IRB Forms

a. Study Protocol.....	44
b. Informed Consent.....	59
c. HIPAA.....	66
d. Screening Form.....	69
e. Baseline Questionnaire.....	71
f. Advertisement.....	85
g. Initial Contact Script.....	86
h. Participation Withdrawal.....	87

APPENDIX D: Weekly Internship Log

a. Internship Journal Log.....	88
--------------------------------	----

CHAPTER I INTRODUCTION

This practicum project was conducted at the University of North Texas Health Science Center Family Medicine Department in The Osteopathic Research Center utilizing PRECISION TEXAS data registry. My supervisor for this six-month project was Cathleen Kearns and Dr. John Licciardone, principal investigator of the research registry, provided the data and assistance with the analysis for this thesis. PRECISION TEXAS is a longitudinal pain registry that collects survey data and biological specimens for ongoing clinical, epidemiological, and interventional studies involving those with subacute and chronic low back pain. For this project, I utilized survey data collected from 321 subjects with varying duration of chronic low back pain. Dr. Ladislav Dory served as the major professor for this project. Dr. Stephen Mathew, Dr. Harlan Jones, and Mrs. Cathleen Kearns served as committee members.

This practicum project sheds light on behavioral contributors that reinforce longer duration of low back pain, physical disability, and emotional distress. Nonspecific low back pain affects millions of people, is the most expensive benign condition to treat, and is the greatest contributor to disability worldwide^{16,22,24}. Treatment of low back pain is difficult due to genetic, anatomical, and psychological components that could contribute to pain progression.

Previous studies demonstrate that psychological disorders and maladaptive coping mechanisms are risk factors in delayed recovery and progression of pain^{26,35}. Pain catastrophizing is a negative coping mechanism that exaggerates perception of pain^{28, 34,35}. Pain catastrophizing is shown to be a major predictor of pain, leading to extended periods of decreased functionality and disability²⁸. Depression and anxiety are diagnosed at high rates in patients with chronic pain and could put those diagnosed at greater risk of catastrophizing³⁵.

The goals of this project were three-fold: 1) To determine if those that have had low back pain for a longer duration exhibited higher pain catastrophizing scores, 2) To examine if there is a higher presence of depression in those with longer low back pain duration and 3) To see if depression is a risk factor for pain catastrophizing. The dependent variables were the pain catastrophizing scores. Predictor variables included duration with low back pain, pain intensity, and depression.

A survey was administered to subjects with chronic low back pain that included questions from the Pain Catastrophizing Scale (PCS) and the PROMIS-29 Quality of Life (QoL) Scale, which measured the extent of depressive symptoms. Pain intensity was measured using a numerical rating scale. To observe if there were variations in pain catastrophizing scores based on duration of pain, I targeted two groups for this study: A) subjects who reported having chronic low back pain from one to five years and B) subjects who reported having chronic low back pain for over five years. An independent t-test was used to compare pain catastrophizing scores between the two groups. An independent t-test was also used to compare PROMIS-29 depression scores between the two groups. A multivariate regression model was used to determine if longer duration with low back pain, higher PROMIS-29 depression scores, and greater pain intensity scores all predicted higher pain catastrophizing scores. Fully-adjusted multivariate analysis included gender and age as possible predictors of pain catastrophizing.

CHAPTER II RESEARCH PROJECT

BACKGROUND

Chronic pain has become an emerging health concern, affecting 1 in 5 U.S. adults⁴. Chronic low back pain is the greatest contributor to disability worldwide^{16,22}. Low back pain is defined as pain below the costal margin (12th ribs) to the lower gluteal folds⁴². It is categorized into three stages: acute (symptoms present <4 weeks), sub-acute (symptoms present 4-12 weeks), and chronic (symptoms present >12 weeks)⁴². A global estimate has shown that of those with low back pain, 38% have had a one year prevalence and 40% have a lifetime prevalence²². As the population ages, these numbers are expected to increase due to age-related degeneration. Chronic low back pain is the most expensive benign condition to treat with an estimated annual cost of 40-50 billion dollars in lost wages, legal cases, and medical bills²⁴.

High-impact chronic pain is defined as chronic pain that oftentimes limits daily life or work activities and is estimated to affect 19.6 million U.S. adults¹⁷. One study demonstrated that back pain patients reported Grade III or Grade IV pain more than any other condition, meaning they suffered high intensity/high disability pain²². This suggests that a large number of low back pain suffers experience pain levels that have a prominent effect on daily functioning. Treating low back pain can be difficult because it is not only dependent on the proper initial intervention, but also on identifying those that are at higher risk for recurrence³². Previous findings elude that physiological processes alone cannot account for the variety of responses to painful stimulation^{19,35}, leading to increased focus on psychosocial contributors to pain perception. Psychological components could be an important influence in pain recurrence. Therefore, behavioral evaluation at pain onset may be advantageous in preventing pain progression.

The negative psychological effects of coping with chronic pain can be debilitating. Previous studies have demonstrated that psychopathologies and maladaptive coping mechanisms are commonly associated with chronic pain³⁵. Pain catastrophizing is an exaggerated, negative perception of pain that facilitates maladaptive coping mechanisms^{7,26,34,35}. Pain catastrophizing is suggested to be one of the most important predictors of pain experience^{1,35,39}. It has also been associated with higher levels of pain intensity and greater risk for fear-avoidance behaviors³⁵, which contribute to prolonged disability.

Pain catastrophizing is composed of three different dimensions: Helplessness, Rumination, and Magnification³⁴. Helplessness refers to the inability to act effectively in response to a painful event. Increased helplessness is seen in a high prevalence of those with depression and is associated with increased pain intensity³⁴. Rumination refers to deep, lingering, considered thought about the pain experience. Magnification is inflation or enhancement of a pain experience. Higher scores in magnification and rumination have been associated with a greater length of disability, even after previous injury is resolved²⁷.

Catastrophizers are at a higher risk of having depression and anxiety, diagnoses that are common among those with a chronic pain condition³⁵. These psychopathologies reinforce a cycle of amplified pain, decreased activity, and emotional distress that impacts quality of life¹⁹. Because of the likeliness of having one of these diagnoses, catastrophizers more susceptible to entering a state of chronic pain^{1,27,34}. Due to the high prevalence of depression seen among patients with chronic low back pain, antidepressants are now becoming more commonly prescribed for pain management¹³.

Evidence suggests that pain catastrophizing can result in higher levels of pain-related fear^{29,36}. Fear-avoidance behavior is when someone refrains from participating in various

activities due to fear that these activities will cause increased pain²¹. This suggests that those with exaggerated thoughts about pain will compensate with decreased activity in order to prevent further painful events. Findings show that fear-avoidance is a result of pain catastrophizing and progression of chronic pain³⁶. Musculoskeletal pain patients that continued to have high catastrophizing and pain-related fear scores post-treatment demonstrated an increased risk of failing to maintain treatment gains²⁶. Because pain catastrophizing is not common in the general population, this aspect can be overlooked at the onset of pain.

Studies have demonstrated a relationship between higher levels of catastrophizing with increased use of analgesic medications² and overall negative health status¹⁸. One chronic low back pain cohort study demonstrated high levels of catastrophizing in half of the subjects²⁷, indicating there might be a higher prevalence among those with low back pain compared to the general population. A significant association was observed between pain catastrophizing and persistent symptoms for those with low back pain but not for shoulder pain⁴¹. A possible reason is that pain catastrophizing may not influence all pain conditions to an equal degree, but targeting those at a greater risk may be beneficial in pain management. The relationship between pain catastrophizing and pain intensity has been observed in a wide range of pain-affiliated disorders^{6,28,31,39}. There is also evidence that catastrophizing impacts the patient-physician interaction, leading to decreased patient satisfaction³⁸. This may impact a patient's treatment expectations and willingness to continue treatments that involve higher efforts, such as physical or behavioral therapy. Identifying and alleviating these cognitions could result better physician-patient communication and higher complacency to novel treatment approaches³⁸.

Pharmacological pain management can be difficult due to medication safety profiles¹³. Due to Washington's Medical Board's relaxation of laws governing opioid prescriptions for

chronic non-cancer pain, opioid medications were commonly used to treat long-term symptoms of low back pain¹¹. Due to the recent unforeseen rise in opioid deaths within the last decade, evidence on long-term use of prescription opioids and their effect in safely improving functioning is limited¹¹. Furthermore, chronic use of opioid prescriptions can easily lead to tolerance and abuse^{2,8}.

Non-pharmacological approaches include spinal manipulation, exercise therapy, and psychotherapies such as Cognitive Behavioral Therapy (CBT) and Acceptance and Commitment Therapy (ACT)^{7,13,42}. CBT is the most commonly used psychotherapy that focuses on identifying negative coping behaviors and creating strategies to change dysfunctional thoughts and behaviors³. There are a variety of CBT treatments that target various mental health disorders and can be administered in several ways (individual face-to-face, group, online therapy)⁴⁰. Recent findings indicate that utilizing a multidisciplinary approach results in a greater improvement of pain compared to an individual therapy approach⁴². Early intervention delivered within months of pain onset has shown to be more effective than later delivery^{19,23}.

Correlations between pain catastrophizing and gender are not clear, although some findings suggest that females tend to have slightly higher pain catastrophizing levels than males¹⁰. A twin study showed that variations in pain catastrophizing scores has an estimated genetic heritability of 37% with 63% of variance due to environmental factors³⁷. This could suggest that proper intervention could alter negative thoughts associated with pain. Early identification of pain catastrophizing and implementation of behavioral intervention predicts long-term improvements and decreased pain¹⁹. This demonstrates possible benefits of early screening for psychological risks in order to prevent progression of pain.

Problem

Catastrophic thinking regarding pain increases the probability that pain will persist for a longer period of time³⁴. Increased pain catastrophizing is seen in patients with subacute and chronic low back pain compared to acute low back pain²⁷. There is not much research on levels of pain catastrophizing several years into chronic stages of low back pain. Previous research observing pain catastrophizing in chronic back pain rarely follows patients' progress past the one-year mark. Pain catastrophizers exhibited a decline in treatment gains as they progress further into chronic stages of pain²⁶. If behavioral intervention delivered closer to the onset of pain has shown a greater impact, may be pain catastrophizing continues to increase as chronic pain progresses and could be contributing to decline in treatment gains. Frustrations with failed treatments and increasing duration of the same levels of pain intensity may promote inaccurate beliefs of pain experience⁴¹. Additionally, maladaptive coping reinforces fear-avoidance behaviors that cause decreased participation in routine activities, thus, negatively impacting the quality of life of those with chronic pain. Depression is seen in high numbers of patients suffering from chronic pain disorders and may contributed added risk to catastrophizing pain. This project will explore if longer duration with chronic low back pain influences pain catastrophizing and depression scores. This project assesses if longer duration of chronic low back pain influences pain catastrophizing and depression scores by exploring different variables that contribute to increased pain catastrophizing, such as measures of pain intensity and depression.

SPECIFIC AIMS AND SIGNIFICANCE

Hypothesis

There will be a positive correlation between pain catastrophizing scores and duration of low back pain. Determine if higher depression and pain intensity measurements influence higher pain catastrophizing scores and if longer duration of low back pain results in higher depression scores that associate with greater pain catastrophizing.

Aim 1

Determine if there is a significant difference in pain catastrophizing and depression scores between groups based on duration of chronic low back pain.

Aim 2

Determine if duration of chronic low back pain, pain intensity, and/or depression are associated with pain catastrophizing.

Aim 3

Determine if duration of chronic low back pain, pain intensity, and/or depression have a specific association with one or more dimension of pain catastrophizing (Rumination, Magnification, or Helplessness).

Significance

A better understanding of psychological influences of chronic low back pain can lead to earlier intervention and improved patient education on effective coping strategies to deal with

pain. While pain catastrophizers represent a small number in the total population, this number becomes larger among hospitalized populations²⁷. This may demonstrate that certain individuals may exhibit hypersensitivity to pain experiences and these lingering thoughts can impact their daily functioning. Exploring therapies that focus on pain catastrophizing may be beneficial in improving recuperation time, decreasing pain intensity, and increasing activity. Targeting psychological influencers of pain experience, like pain catastrophizing, could provide a more well-rounded approach to pain management. This holistic approach would benefit future patients by decreasing the need for opioid prescriptions, therefore decreasing opportunity for opioid addiction and abuse.

EXPERIMENTAL DESIGN: METHODS AND MATERIALS

Study Design

Self-reported questionnaires were used in this study. Participants were recruited through online advertisements via Facebook, community news letters, and flyers posted in UNTHSC clinics and various surrounding establishments. The study was approved by the Institutional Review Board (IRB) of the University of North Texas Health Science Center. The study population consisted of subjects including those who reported having chronic low back pain for one or more years. Subjects were divided into two groups, those that report having had low back pain for one to five years and those that report having had low back pain for more than five years.

Population and Sample Size

Sample size consisted of 321 male and female subjects. There were 107 subjects that reported having had low back pain for 1-5 years and 214 subjects that reported having had low back pain for over 5 years. All participants are from the Dallas/Fort Worth Metroplex.

Inclusion Criteria

- Subject must be between 21 to 79 years of age
- Subjects must report having low back pain at least half the days of the past two months
- Subjects must report having a physician, must be able to tell study staff if physician is a MD or DO, and must report having this physician for a period of at least one to three months
- Subjects must be able to communicate and complete the surveys in English

Exclusion Criteria

- Pregnancy
- Incarcerated or institutionalized

Methods and Data collection

Information was collected from male and female subjects in two groups: Those that have had chronic low back pain for one to five years and those with chronic low back pain for more than five years. After obtaining informed consent, participants were administered a computer survey collecting self-reported, de-identified information on various aspects of their low back pain. Data collected included measurements for pain catastrophizing, pain intensity, and depression.

Pain Catastrophizing Scale(PCS)

Subjects completed the Pain Catastrophizing Scale (PCS) questionnaire, consisting of 13 questions measuring the three categories of pain catastrophizing: Rumination, Magnification, and Helplessness. Each question is scored on a 5-point scale with the end points (0) representing never having these thoughts and (4) representing having these thoughts all the time³⁴. Composite

score ranges from 0-52, with previous studies showing over thirty points is statistically significance for levels of catastrophizing¹². Questions assigned to each category as follows:

- a) Helplessness: Questions 1, 2, 3, 4, 5, and 12 (Score Range: 0-24)
- b) Rumination: Questions 8, 9, 10, and 11(Score Range: 0-16)
- c) Magnification: Questions 6, 7, 13 (Score Range 0-12)

Visual Analogue Numerical Rating Scale

Visual Analogue Scale (VAS) was used to measure pain intensity. Subjects were asked to rate their average pain intensity within the last week. Possible pain intensity ranged from 0-10, with the end points (0) representing no pain and (10) representing the worst possible pain²⁵.

PROMIS-29 Profile v2.0

Depression was measured through the PROMIS-29 Quality of Life survey, asking participants to rank their current depressive symptoms on a scale of 1-5, with the highest raw score being 20. The raw score is then converted into a T-Score based on the mean of the general population reference sample. A normal T-score range is 50 ± 10 , meaning a score of over 60 is demonstrates the presence of depressive symptoms. Raw score range between 4-11 are considered to be within normal range for depression¹⁴.

Statistical Analysis

An independent samples t-test was done to evaluate if there is a difference between mean PCS based on duration with low back pain. An independent samples t-test was also used to determine a relationship between depression and duration with low back pain. Equal variance across the two groups was assumed using Levene's Test for Equality of Variances. Differences were deemed statistically significant when $p < 0.05$.

A multivariate regression model was used to determine which predictor variables had an association with increased pain catastrophizing scores. The predictor variables examined were duration of back pain, pain intensity, and depression. A fully-adjusted multivariate analysis also included gender and age as co-variants in pain catastrophizing. Both an independent samples t-test and a multivariate regression were also completed for each individual dimension of pain catastrophizing (helplessness, rumination, and magnification).

RESULTS

Subject Demographics

Survey data was collected from a sample of 321 participants divided into two groups based on duration with chronic low back pain. This population consists of 68.2% Caucasian, 27.7% African American, and 4.1% that identified as another race (*see Table 1*). Group one consisted of subjects that had low back pain for one to five years and composited of 33 males and 74 females (N= 107). The mean age of this group was 53.4 ± 11.4 with subjects ranging from 23 to 76 years of age. Group two consisted of subjects that had low back pain for over five years and composited of 78 males and 136 females (N=214). The mean age of this group was 54.4 ± 11.5 with subjects ranging from 21 to 77 years of age. In the total sample, 23% (n=74) reported receiving disability or workers' compensation benefits because they were unable to work due to their low back pain.

Subjects reported all treatments previously received or participated in for low back pain. As shown in *Table 2*, the percentage that received/participated in each non-pharmaceutical treatment are as follows: exercise therapy 56%, massage therapy 45%, spinal manipulation 41%, yoga 23%, acupuncture 16%, cognitive-behavioral therapy(CBT) 7.2%. The average number of different treatments attempted was two. Data were also collected on current use of opioid

prescriptions and/or non-steroidal anti-inflammatory medications for pain management (*Table 3*). In group one, 27% reported current use of prescription opioids and 63% reported current use of non-steroidal anti-inflammatory medications (NSAIDs). In group two, 35% reported current use of prescription opioids and 63% reported current use of NSAIDs for pain relief. Breakdown of demographics (*Table 1*), treatments (*Table 2*), and medications (*Table 3*) by group can be seen below.

Table 1: Population Demographics

<u>Population Demographics</u>		<u>Group 1:</u>		<u>Group 2:</u>	
		<i>LBP 1-5 years</i>		<i>LBP over 5 years</i>	
		n	%	n	%
Total (N)		107	100%	214	100%
Age	Mean age	53.4	—	54.4	—
	Age Range	23-76	—	21-77	—
Gender	Male	33	31%	78	36%
	Female	74	69%	136	64%
Race	White/Caucasian	74	69%	145	68%
	Black/African American	28	26%	61	29%
	Native Hawaiian/Pacific Islander	0	—	1	0.50%
	Asian	2	2.0%	5	2.0%
	American Indian/Alaskan Native	3	3.0%	2	0.90%
Ethnicity	Hispanic/Latino	18	17%	27	13%
	Non-Hispanic/Latino	89	83%	187	87%

Disability	Received Disability/Workers' Compensation Benefits	19	18%	55	26%
-------------------	--	----	-----	----	-----

Group one represents those with duration of LBP 1-5 years and group two represents those with low back pain for over 5 years. Total sample size for group one and group two are N=107 and N= 214, respectively. Rows are categorized by age, gender, race, ethnicity, and those that have received disability/workers' compensation due to back pain. Columns labeled n represents number per group and the columns labeled % represent the percentage of individuals per group in a designated category. Age (in years) is given as the mean age per group along with the age range of participants in each group.

Table 2: Non-Pharmaceutical Treatments

<u>Treatments</u>	<u>Group 1: LBP 1-5 yrs.</u> (N=107)		<u>Group 2: LBP over 5 yrs.</u> (N=214)		<u>Total Sample</u> (N=321)	
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
<i>Exercise Therapy</i>	53	50%	127	59%	180	56%
<i>Massage Therapy</i>	47	44%	98	46%	145	45%
<i>Spinal Manipulation</i>	39	36%	93	43%	132	41%
<i>Yoga</i>	29	27%	46	21%	75	23%
<i>Acupuncture</i>	11	10%	40	19%	51	16%
<i>CBT</i>	7	6.5%	16	7.5%	23	7.2%

Subjects selected all treatments they are or previously have ever received/participated in. Group one had a mean of 1.74 ± 1.44 received treatments per person. Group two had a mean of 1.96 ± 1.38 received treatments per person. Rows show the number and percentage of those that have received/participated in the following treatments: Exercise Therapy at a Facility, Massage Therapy, Spinal Manipulation, Yoga, Acupuncture, and Cognitive Behavioral Therapy(CBT). Columns show the number (n) and percentage (%) of treatment participants in group one, group two, and total sample, respectively.

Table 3: Current Medications used for pain management

<u>Current Medication</u>	<u>Group 1: LBP 1-5 yrs.</u>		<u>Group 2: LBP over 5 yrs.</u>		<u>Total Sample</u>	
<u>Use</u>	N=107		N=214		N=321	
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
Opioid Painkillers	29	27%	74	35%	103	32%
NSAIDs	67	63%	139	65%	206	64%

Below is the number (n) and percentage (%) of subjects that are currently using prescription opioids and/or nonsteroidal anti-inflammatory drugs (NSAIDs) for pain management. Columns represent data from group one (N=107), group two (N=214), and the combined total population (N=321). Those with low back pain for over five years had a larger percentage of opioid (35%) and NSAID (65%) users compared to 1-5 years.

Aim 1: Determine if there is a significant difference in pain catastrophizing and depression scores between groups based on duration of chronic low back pain.

Pain catastrophizing scores were recorded for subjects and the mean scores of each group are shown in *Table 4*. Group one consisted of people with low back pain for one to five years with a mean pain catastrophizing score of 16.5 ± 13.9 . Group two consisted of people with low back pain for over five years with a mean pain catastrophizing score of 18.9 ± 14.4 . An independent samples t-test was performed comparing pain catastrophizing scores between the two groups based on low back pain duration. The t-test results (*Table 5*) showed that while scores were higher in those who reported having low back pain for more than five years, the data did not show a significant difference due to low back pain duration ($p=0.16$).

Data regarding diagnosis of depression and PROMIS-29 scores between groups can be seen in *Tables 6a* and *6b*, respectively. Depression was previously diagnosed in about half ($n=155$) of our total subject population, with a slightly higher percentage of diagnosed in group

two. PROMIS-29 mean T-scores demonstrated insignificant variance between the groups, averaging within a normal range for both groups. Independent samples t-test did not show statistical significant difference between duration with chronic low back pain and PROMIS-29 depression scores.

Table 4: Group Statistic for Mean Pain Catastrophizing score based on duration of chronic low back pain.

DURATION WITH LOW BACK PAIN	MEAN PCS	STD. DEVIATION	ERROR MEAN
Group 1: 1-5 years	16.5	13.9	1.34
Group 2: More than 5 years	18.9	14.4	0.987

Group one (N=107) consists of those with low back pain for 1-5 years with a mean PCS of 16.5. Group two (N=214) represents those with low back pain for over 5 years with a mean of 18.9.

Table 5: Independent t-test results for Pain Catastrophizing scores based on duration of chronic low back pain

	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Mean Difference	95% Confidence interval of the Difference	
						Lower	Upper
Total PCS	-1.41	319	0.161	-2.37	1.69	-5.70	0.95

Results showed no statistically significant differences in mean pain catastrophizing scores(PCS) between those that have had low back pain for one to five years and those that have had low back pain for over five years.

Table 6a: Number of subjects previously diagnosed with depression in each group

	<u>Group 1:</u>		<u>Group 2:</u>		<u>Total Sample</u>	
	N=107		N=214		N=321	
	n	%	n	%	n	%
Depression Diagnosis	48	45%	107	50%	155	48%

Number (n) and percentage (%) of subjects that reported having been diagnosed with depression. Columns consist of group one (N=107), group two (N=214), and the total population(N=321). Roughly 50% of subjects in each group reported being diagnosed with depression.

Table 6b: Mean T-scores from the PROMIS-29 Quality of Life Questionnaire and the Numerical Rating scale

	Mean	Std. Deviation	Std. Error Mean
GROUP 1: LBP 1-5 YRS (N=107)	52.1	9.54	0.922
GROUP 2: LBP OVER 5 YRS (N=214)	52.6	9.53	0.652

	t	df	Sig.	Mean Diff.	Std. Error Diff.	95% CI of the Diff	
						Lower	Upper
PROMIS-29 SCORE	-0.376	319	0.707	-0.425	1.13	-2.65	-1.80

A section from the PROMIS-29 QoL questionnaire measured the extent of depressive symptoms in subjects over the past 7 days. Mean scores for group one and group two are 52.1 and 52.6, respectively. Both scores are shown to be in normal range ($T=50 \pm 10$). Independent samples t-test demonstrated no statistical significance between duration and PROMIS-29 scores.

Aim 2: Determine if duration of chronic low back pain, pain intensity, and/or depression are associated with pain catastrophizing.

The co-variants for the partially-adjusted multivariate analysis consisted of duration with chronic low back pain, PROMIS-29 depression scores, and pain intensity (Table 7a). Subjects with a longer duration of low back pain had slightly higher pain catastrophizing scores, but the scores were not statistically significant. Findings demonstrated that pain intensity and depression scores were better predictors of pain catastrophizing ($p < 0.001$), meaning that those with higher scores for pain intensity or depression were more likely to also have higher pain catastrophizing scores. These results confirm previous literature of an association between pain catastrophizing, pain intensity, and depression.

In the fully-adjusted multivariate analysis (Table 7b), the inclusion of gender and age as co-variants showed novel findings that differed from previous studies. The data showed an inverse relationship between age and pain catastrophizing scores. This means that as subjects' age increased, their PCS scores decreased. In this study, PCS scores were lower in female

subjects compared to males, contradicting previous findings. However, neither age or gender showed a statistically significant association with pain catastrophizing.

Table 7a: Multivariate regression for the predictors disease duration, pain intensity, and depression

	Unstandardized Coefficients		Standardized Coefficients	<i>t</i>	Sig. (<i>p</i>)
	<i>B</i>	Std. Error	β		
<i>Duration with LBP</i>	1.51	1.28	0.050	1.18	0.239
<i>Pain Intensity</i>	1.89	0.310	0.273	6.11	<0.001
<i>Depression Scores</i>	0.774	0.067	0.516	11.6	<0.001

No statistically significant association was observed between duration of low back pain and PCS. Statistical significance ($p < 0.05$) was observed between both pain intensity ($p < 0.001$) and depression ($p < 0.001$) being associated with pain catastrophizing.

Table 7b: Fully-adjusted multivariate regression model incorporates age and gender as variables of PCS.

Predictors	Unstandardized Coefficients		Standardized Coefficients	<i>t</i>	Sig. (<i>p</i>)
	<i>B</i>	Std. Error	β		
<i>Duration with LBP</i>	1.51	1.27	0.050	1.18	0.238
<i>Pain intensity</i>	1.98	0.312	0.285	6.34	<0.001
<i>Depression Scores</i>	0.762	0.067	0.508	11.39	<0.001
<i>Age</i>	-0.097	0.052	-0.078	-1.86	0.064
<i>Gender</i>	-1.37	1.27	-0.046	-1.08	0.280

Age and pain catastrophizing were shown to have an inverse relationship, meaning as subjects aged, their PCS scores decreased. ($\beta = -0.078$). Males had slightly higher PCS compared to females, but not statistically significant.

Aim 3: Determine if duration of low back pain, pain intensity, and/or depression have a specific association with one or more dimension of pain catastrophizing (Rumination, Magnification, or Helplessness).

Mean scores for each dimension of pain catastrophizing can be seen in *Table 8*. Scores for rumination, magnification, and helplessness were slightly higher in those with low back pain for over five years compared to those with low back pain for one to five years. Helplessness was shown to have the highest increase between the groups, but neither category was statistically significant (*Table 9*).

Both, pain intensity and depression had a statistically significant association with rumination, magnification, and helplessness. (*Table 10*). There is no evidence suggesting a specific association for one dimension over another. Interestingly, age had an inverse association with magnification that was deemed statistically significant ($p=0.008$). This suggests that as age increased, magnification of pain response decreased (*Table 10b*).

Table 8: Group statistics of mean PCS scores for Rumination, Magnification, and Helplessness

	Duration	Mean	Std. Dev	Std. Error Mean
Rumination	1-5 years	6.07	5.12	0.495
	More than 5 years	6.87	5.37	0.367
Magnification	1-5 years	3.63	3.27	0.316
	More than 5 years	4.06	3.59	0.246
Helplessness	1-5 years	6.81	6.20	0.599
	More than 5 years	7.95	6.58	0.450

Mean PCS for each dimension is shown for each group based on duration of LBP. Subjects with low back pain for over five years had slightly higher mean scores on all the dimensions of pain catastrophizing compared to subjects with low back pain for one to five years. High standard deviations for all three categories indicate a wide range of individual scores. Possible score ranges are: Rumination (0-16), Magnification (0-12, Helplessness (0-24)

Table 9: Independent t-test for each dimension of Pain Catastrophizing between groups

	t	df	Sig (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
						<i>Lower</i>	<i>Upper</i>
Rumination	-1.283	319	0.200	-0.804	0.626	-2.04	0.428
Magnification	-1.05	319	0.293	-0.435	0.413	-1.25	0.378
Helplessness	-1.49	319	0.138	-1.14	0.764	-2.64	0.369

Mean helplessness exhibited the largest variance in scores between the two groups compared to other dimensions. Scores for all three categories were higher for group two compared to group one but did not show statistical significance.

Table 10: Fully-adjusted multivariate regression for Rumination, Magnification and Helplessness

<u>10a: Rumination</u>	<i>Unstandardized Coefficients</i>		<i>Standardized Coefficients</i>	<i>t</i>	<i>Sig.(p)</i>
	<i>B</i>	<i>Std. Error</i>	β		
<i>LBP Duration</i>	0.460	0.508	0.041	0.907	0.365
<i>Pain Intensity</i>	0.763	0.124	0.296	6.14	<0.001
<i>Depression</i>	0.236	0.027	0.424	8.84	<0.001
<i>Age</i>	-0.021	0.021	-0.045	-0.998	0.319
<i>Gender</i>	-0.838	0.506	-0.075	-1.66	0.098
<u>10b: Magnification</u>	<i>Unstandardized Coefficients</i>		<i>Standardized Coefficients</i>	<i>t</i>	<i>Sig.(p)</i>
	<i>B</i>	<i>Std. Error</i>	β		
<i>LBP Duration</i>	0.295	0.332	0.040	0.890	0.374
<i>Pain Intensity</i>	0.281	0.081	0.166	3.47	0.001
<i>Depression</i>	0.189	0.017	0.517	10.87	<0.001
<i>Age</i>	-0.036	0.014	-0.119	-2.66	0.008
<i>Gender</i>	-0.275	0.330	-0.038	-0.833	0.406
<u>10c: Helplessness</u>	<i>Unstandardized Coefficients</i>		<i>Standardized Coefficients</i>	<i>t</i>	<i>Sig.(p)</i>
	<i>B</i>	<i>Std. Error</i>	β		
<i>LBP Duration</i>	0.752	0.580	0.055	1.30	0.195
<i>Pain Intensity</i>	0.934	0.142	0.297	6.59	<0.001
<i>Depression</i>	0.337	0.030	0.496	11.1	<0.001
<i>Age</i>	-0.040	0.024	-0.072	-1.70	0.091
<i>Gender</i>	-0.261	0.577	-0.019	-0.452	0.652

Pain intensity and depression were both statistically significant predictors for all three variables of pain catastrophizing. Meaning that, higher pain intensity and depression scores were associated with higher PCS scores in Rumination(10a), Magnification(10b), and Helplessness(10c).

DISCUSSION AND CONCLUDING THOUGHTS

The purpose of this study was to explore the psychosocial risk factors that may contribute to chronic, nonspecific low back pain. There are multiple components to address when treating chronic pain and targeting a combination of aspects has demonstrated the strongest chance for rehabilitation or decreased pain^{13,42}. Low back pain is considered chronic when pain continues for more than three months, but for many, it usually spans several years^{27,42}. A novel aspect of this research in comparison with previous studies is evaluating low back pain patients several years into their disease progression. As the duration of pain increases, patients are likely to experience emotional distress from repeated failed treatments, prolonged discomfort, and decreased ability to participate in enjoyable activities. This distress may prompt further exaggeration of negative pain perception.

The premise was that if responses to pain are so diverse that physiological aspects alone could not account for the variance, maybe psychological contributors could be responsible. For instance, pain catastrophizing has been linked to fear-avoidance behavior, which causes decreased mobility and prolongs disability³³. If behavioral interventions in the early stages of disease presented better results²³, maybe processes involved in pain perception have a greater impact as duration of pain increases and become less affected by treatment. Subjects with higher pain catastrophizing scores were likely to also rank higher pain intensity, confirming previous evidence. However, in this study, duration of low back pain did not correlate with increased pain catastrophizing in a statistically significant manner. An interesting observation was that age had an inverse effect on pain catastrophizing scores, demonstrating that our population presented with lower pain catastrophizing scores as their age increased. This may be because the elderly

become accustomed to the prolonged pain or suffer from a series of ailments that come with the aging process and become accustomed to it.

Pain catastrophizing has been consistently associated with heightened pain experience³⁵. There is evidence that the characteristic of pain catastrophizing is not necessarily the result of injury (or painful stimulus) experience but that it may emerge early in life³⁵. My findings demonstrated that the presence of depressive symptoms correlated with higher levels of pain catastrophizing ($p < 0.0001$), similar to that of previous research. Patients that have higher on levels of pain intensity and depression could be considered at greater risk of negative thoughts and maladaptive coping. Fear-avoidance is a behavioral component that is linked to pain catastrophizing where one refrains from initiating behaviors or actions out of fear it will promote more pain³³. Decreasing physical activity is contrary to the recommendations of the American College of Physicians, which promotes daily activity over bed rest in improving low back pain⁵. Those at risk of pain catastrophizing and pain-related fear have an increased likeliness to abstain from daily activities and have a greater chance of long-term disability.

Data did not show significant differences in pain catastrophizing and depression scores, based on different durations of low back pain. When dimensions of PCS were analyzed, again no mean difference was determined between the two groups. However, there was variability between subjects scores on every dimension of PCS, showing that pain perception may not be easy to generalize. Adapting an individualistic approach when treating low back pain may be beneficial in identifying those that are at risk of psychological influences in progression of pain. Pain catastrophizers were shown to have a decline in treatment gains as they progress further into chronic stages of pain²⁶. This may be due to lack of motivation after numerous attempts of various treatments that were not successful in the past. Early identification is key for this

population to gain the most treatment benefits. Currently, psychological intervention for pain are not at the frontline of treatment options, still being used a last resort despite reports of success¹⁹. In this sample, almost 50% had a previous diagnosis of depression, making them at risk for pain catastrophizing. However, only 7.2% had previously participated in Cognitive-Behavioral Therapy. Early screening for psychological risks in those with onset of low back pain could assist in identifying those at risk of maladaptive perceptions. This can help physicians intervene before pain progresses to a chronic state, possibly lead to a reduction in opioid prescriptions, decreased pain intensity, and decreased episodes of pain.

Limitations

One of the limitations is that medications were not controlled for in the study. Due to availability of over-the-counter analgesics, it was difficult to find a large enough sample size that were not using any medication for minor pain relief. Pain catastrophizing measure the degree one has certain thoughts while experiencing pain and do not require the presence of pain to be measured. Thus, PCS scores are minimally affected by current medication use. However, medication use could affect a participant's response to pain intensity and extent of depressive symptoms.

A second limitation is that subjects self-report their average pain intensity over a seven-day period. This may not be an accurate representation of pain in one given episode. Instead, a cold pressor procedure, (where the number of seconds held in cold water serves as a recording for pain intensity) could be a more measurable approach. Due to time constraints, such a test could not be performed on such a large group of subjects.

A third limitation is that all information regarding pain and depression was collected from one survey. A better approach would be a longitudinal study that tracks changes of pain

intensity, depression, and catastrophizing of chronic low back pain over a period of time. Due to time constraints, this was not feasible in such a large sample size.

Finally, a physical contributor to low back pain is body mass index. Overweight and obese subjects may have a decreased mobility and compression of internal structures due to excess body fat. Therefore, reduced activity could be accounted for an inability due to physical size, not avoidance due to fear of pain. This could be another contributor to prolonged disability. Controlling for body mass index and other comorbidities may give a more accurate comparison of pain intensity due to psychological attributes.

Future Research

Pain management requires efforts in targeting the multiple contributors to chronic low back pain. A complete understanding of all factors and the magnitude of their role in low back pain is still unclear. Increasing research demonstrates that psychosocial components have a significant role in predicting pain and may lead to the progression from acute to chronic pain. Future research involving longitudinal studies of pain catastrophizers and pain progression could provide further insight into pain processes for those at risk of displaying maladaptive coping mechanisms. This could potentially lead to better resources in identifying those likely of having exaggerated pain perceptions and provide early intervention.

CHAPTER III

INTERNSHIP EXPERIENCE

INTERNSHIP SITE

This internship was conducted at The Osteopathic Research Center (ORC) with the PRECISION TEXAS Pain Research Registry (*Pain Registry for Epidemiological, Clinical, and Interventional Studies in North Texas*). The site is located at the University of Texas Health Science Center in Fort Worth, Texas. The ORC Executive Director is John Licciardone, DO, MS, MBA, with Ms. Cathleen Kearns as the Research Assistant Director. Samantha Johnson is the lead research coordinator, along with myself and Dina O'Brien who also serve as project coordinators. Genetics processing is handled by Nicole Phillips, PhD, ORC Director of Genomic Research.

Current Studies

The goal of the registry (abbreviated as PTX) is to recruit 1,000 subjects that suffer from chronic low back pain. In this ongoing study, quarterly surveys are administered to subjects to collect information on various aspects of their condition including co-morbid diagnoses, treatments previously received, current medications, psychosocial aspects, and physician experience (empathy, communication and satisfaction). One-time blood and saliva samples are collected from each participant and are utilized for genetic and biomarker analysis.

A sub-study of PRECISION TEXAS, *The Safety and Efficacy of Opioids in Patients with Low Back Pain: A Registry-Based Cohort Study to Compare Single- and Multi-Gene Approaches to Precision Medicine Prescribing vs. Usual Care (IPS)*, is a four-week long study that collects information on pain sensitivity and tracks weekly medications changes. Once subjects are enrolled into PTX, they are eligible to participate in IPS. Most subjects begin the sub-study the

week following their first PTX quarterly visit. The biological sample collected for PTX will also be used for IPS to analyze genes associated with codeine metabolism.

The Health Status Study is the newest addition to PRECISION TEXAS. Participants in this study will serve as control subjects for the PTX study. Subjects complete a one-time visit that includes a modified baseline survey (similar to the PTX baseline) as well as blood and saliva samples used for genetic purposes.

There are no diagnosis or treatments administered in any of the current studies at PRECISION TEXAS.

Genetic and Biomarker Analysis

De-identified blood and saliva samples collected for each subject are stored in a genetic facility at the Center for BioHealth at UNTHSC. Saliva samples are collected using ORAGENE Discovery collection vials and genetic information is extracted for analysis. Blood samples are obtained through Quest Diagnostics, collecting two lavender tubes and one tiger top (red/black) tube. The three tubes of blood are then spun down and 2 ml aliquots of whole blood, serum, plasma and buffy coat are preserved in the -80 degree freezer until needed for analysis. Blood samples are used for biomarker analysis but can also be used for genetic analysis if the saliva sample does not suffice.

Once DNA is extracted and quantified, it is amplified by DNA polymerase chain reaction, autosomal, Y chromosomal, mitochondrial DNA, insertions, deletions and other available SNP DNA markers. SNP testing is done on relevant genes that play a role in opioid and NSAID drug metabolism. Sequence data is visualized by capillary electrophoresis using an Amplified Biosystems Genetic Analyzer or real-time PCR using an Amplified Biosystems 7300/7500. All genetic data are kept on secure, password protected computers within the facility.

INTERNSHIP ACTIVITY AND EXPERIENCE

Before beginning my internship, I completed CITI training, Blood Borne Pathogen Training, and Research Conflict of Interest Training and Annual Disclosure. My internship began with meeting Ms. Cathleen Kearns, where I was given the current study protocol, informed consent, and the Health Insurance Portability and Accountability Act (HIPAA) document, and printed handouts of all quarterly questionnaires administered. After a brief study overview, I began shadowing project coordinator, Samantha Johnson, during subject encounters. I learned the details of subject recruitment and qualifications, data collection, and compensation.

Daily Tasks

An important duty of a coordinator was to keep up-to-date subject records by documenting the details of subject encounters both in the subject's chart and the enrollment log. The enrollment log is a master spreadsheet contacting each subject's study progress and uniquely assigned identification number, contact information, and encounters dates. Subjects are scheduled to complete a survey every three months and I was responsible for scheduling subjects within the one-month time frame they are eligible to complete the survey. Updating the enrollment log after each encounter was crucial to ensure staff members knew of each subject's progress. Keeping this document as current as possible prevented missed visits and lost-to-follow-up subjects. My daily office tasks include making subject reminder calls, preparing subject folders for the day, checking the ORC Study Operations email, and exporting completed surveys from Qualtrics onto the ORC server. I was also responsible for reviewing Health Status Control screenings to determine qualifying participants and contacting them to provide additional information and schedule a visit.

Quality Assurance and Preparation for Institutional Review Board annual review

I witnessed the importance of organization and attention to detail while preparing for annual Institutional Review Board (IRB) Continuing Review. Each study is approved to operate for one year, at which time, a progress report is submitted to the board for review and continuing approval. I assisted with organizing the subjects' electronic and paper charts by updating dividers and replacing outdated forms with newly approved ones. For auditing purposes, all folders needed to be uniform with completed/signed paperwork and coordinator initials next to each documented visit. Prior to my arrival, changes were made to the study that involved migrating from compensation using physical and electronic gift cards to a web-based debit card system (Greenphire ClinCard). Previously enrolled subjects needed to be informed of these changes and were required to re-consent before they could continue participation. If a subject completed a survey without signing the new consent document, it would result in a protocol violation. My duties required diligence when updating charts prior to subject visits and noting which subjects still needed to re-consent.

Submitting documents to the IRB was a frequent occurrence as the study began using new methods of advertisement. I became familiar with the UNTHSC IRB office by dropping off documents for review. In preparing for the continuing review, I observed how Samantha prepared multiple copies of every document as requested by the IRB. I assisted in completing subject demographic forms needed for submission by tallying subjects by gender, race, ethnicity, and status in study (enrolled/lost to follow up/withdrew). Midway through my internship experience, the IRB partially converted to an electronic format and I learned how to upload documents through the new computerized system.

Subject Recruitment:

For subject recruitment, PRECISION TEXAS utilizes various media outlets as well as printed flyers dispersed throughout the UNTHSC Patient Care Center and surrounding establishments. I replenished flyers on every floor of the clinic monthly, and occasionally spent time circulating flyers to neighboring businesses and community boards in Fort Worth. Advertisements were also broadcasted on UNTHSC's Daily News Email, Star Telegram, and Facebook. The Osteopathic Research Center was present at several community events, spreading awareness of the registry and screening interested subjects. The events I attended include the Tarrant County Back-to-School Round Up, Roger Evans Community Center Back-to-School Event, and the Naval Air Station Health and Fitness Expo.

Screening Subjects

Subjects can see if they qualify for either the PRECISION TEXAS or the Health Status study by completing a screening survey online or by phone. Screenings are administered through Qualtrics and qualifying participants are later contacted by phone with more study details. I participated in screening both PTX and Health Status subjects, but my main responsibility was focused on filtering through Health Status screenings. I dedicated time weekly to check all screenings and to contact qualifying participants. Once a visit was scheduled, I was also in charge of scheduling a Quest Diagnostics lab appointment and send the subject a detailed email of their scheduled appointment.

Subject Enrollment: The Baseline Visit

First, the subject is given an overview of the study and any further questions are answered by the coordinator before subject signs the informed consent document. They must

also complete a HIPAA authorization form and a W9 form. Once all documentation is signed, the baseline visit progresses as follows:

1. Make a copy of the valid government-issued photo identification
2. Record subject's list of medications taken for low back pain
3. Saliva sample collected in visit room and blood sample collected at Quest Diagnostics. Hand biological samples to genetics lab personnel once obtained.
4. Measure subject's height and weight (if needed)
5. Administer baseline survey through Qualtrics
6. Issue and register ClinCard and compensate subject
7. Update subject contact information
8. Make chart note regarding visit

Upon return to the office, PDF the survey and scan the subject chart to place on data drive. This provides a redundant data source in the event of a fire or other issue that may occur where the charts are physically stored. Copies of the charts, the enrollment log, and other important study documents are stored on a shared data drive that is housed in Denton. Qualtrics surveys are stored by Qualtrics in a cloud-based location.

Subject Encounters

As a project coordinator, I completed subject visits for the PRECISION TEXAS, IPS, and Health Status study. These visits could be completed online via email, by phone, or in-person. One of my responsibilities includes verifying that participants have signed the newest consent form as appropriate, and that changes are explained in detail prior to re-consent. Duties include thoroughly explaining the informed consent and HIPAA forms to the subject, administering surveys, and recording these visits in a subject's charge as well as in the master

enrollment log for the study. When blood and saliva samples are collected (baseline visits only), I was responsible for contacting Dr. Nicole Phillip's genetic laboratory to have the specimen picked up and processed within thirty minutes of collection. At the end of a subject's visit, I registered the ClinCard card and compensated the subject accordingly.

My Internship Experience

Throughout this internship, I witnessed the amount of obligation and effort needed to keep a clinical trial valid. I learned how significant proper documentation and record keeping was for adhering to the Institutional Review Board regulations. As a coordinator, I always referred to the protocol in order to maintain data creditability. I learned appropriate language when answering any questions subjects had regarding the survey questions to ensure I would not bring in a bias with my own interpretations. My attention to detail has becoming stronger as a result. Not only did I acquire the skills of proficient research coordinator, but was capable of teaching others. During my time here, I assisted in training Dina O'Brien as well as several students that were part of our team.

My time at PRECISION TEXAS benefitted me in more ways than just learning how to collect meaningful data. Aside from becoming well-informed on research processes, I was able to witness innovative approaches to research like implementing a debit card payment system for subject compensation. Our team found new ways to reach potential participants by advertising on Facebook and Twitter. Remote processes were also implemented to adhere to our participants' busy schedules. Since I began my internship, we received approval to start enrolling subjects into IPS remotely, by sending needed paperwork to their confirmed email and using the subject's signature from their PTX consent form to verify identification. Many of these processes were

developed through collaboration at monthly PRECISION TEXAS meetings involving a larger research team.

As the study expands, we have begun working on remotely consenting subjects into PTX through DocuSign, a HIPAA compliant system that allows subjects to sign forms electronically. This is the first step taken to providing remote baseline visits, and will allow the registry to expand to the entire Texas population. Future expansions that have been discussed include moving backend study processes and data collection into REDCap (Research Electronic Data Capture), a secure web software that manages study processes and data. This will not only reduce survey errors by personalizing survey links to each individual subject number, but will also allow subjects to schedule appointments electronically, decreasing the amount of missed visits and lost-to-follow ups. Using REDCap will also reduce the amount of time required by study personnel to manage the processes of the project. Because this is a longitudinal registry project, the number of follow-up encounters continues to increase each month as the number of subjects increases. I met with members of the technology knowledge management team along with Ms. Johnson and Ms. Kearns to explore the options for remote consenting and study management.

The amount of knowledge I have gained in my short time here is nothing short of remarkable. PRECISION TEXAS has a dedicated research team that is always looking to improve the research process and obtain data with accuracy and validity. I greatly appreciate those that assisted in developing my skills as a research coordinator and allowing me to be involved in such an innovative and expanding project at the University of North Texas Health Science Center.

References:

1. Archer, K., Abraham, C., et Al. Cognitive-Behavioral Determinants of Pain and Disability Two Years after Traumatic Injury: A Cross Sectional Study. *The Journal of Trauma and Acute Care Surgery*. 72(2):473–479, FEB 2012 DOI: 10.1097/TA.0b013e3182245ece
2. Ballantyne JC., Shin NS., Efficacy of opioids for chronic pain: a review of the evidence. *Clin J Pain* 2008; 24(6):469-78
3. Beck JS. Cognitive behavior therapy: Basics and beyond 2nd edition. 2011. p19–20.
4. CDC. Prevalence of Chronic Pain and High-Impact Chronic Pain Among Adults- United States, 2016. *MMWR Morb Mortal Wkly Rep* 2018; 67:1001-6
5. Chou R., Qaseem A., Snow V. et al. Diagnosis and Treatment of Low Back Pain: A Joint Clinical Practice Guideline from the American College of Physicians and the American Pain Society. *Annals of Internal Medicine* 2007; 147: 478-490
6. Dave AJ, Selzer F, Losina E, et al. Is There an Association Between Whole-body Pain with Osteoarthritis-related Knee Pain, Pain Catastrophizing, and Mental Health? *Clinical Orthopaedics and Related Research*. 2015;473(12):3894-3902. doi:10.1007/s11999-015-4575-4.
7. De Boer M., Steinhagen H., Versteegen G., et al. Mindfulness, Acceptance and Catastrophizing in Chronic Pain. *PLoS ONE* 2014 9(1): e87445. Doi:10.1371/journal.pone.0087445
8. Eric Garland. Treating chronic pain: the need for non-opioid options. *Expert Rev. Clin. Pharmacol*. 2014; 7(5): 545-550

9. Federation of State Medical Boards of the US Model guidelines for the use of controlled substances for the treatment of pain: A policy document of the Federation of State Medical Boards of the United States, Inc Dallas, TX 1998
10. Forsythe L., Thorn B., Day M., Shelby G. Race and Sex differences in Primary Appraisals, Catastrophizing, and Experimental Pain Outcomes. *The Journal of Pain* 2011, 12(5): 563-572
11. Franklin G., Rahman E., Turner J., et al. Opioid Use for Chronic Low Back Pain: A Prospective, Population-based Study Among Injured Workers in Washington State, 2002-2005. *The Clinical Journal of Pain* 2009; 25:743-751 doi: 10.1097/AJP.0b013e3181b01710
12. Gatchel R., Neblett, R. Pain Catastrophizing: What Clinicians Need to Know. *PPM* 2017;15(6)
13. Gouveia N., Rodrigues A., et al. The Use of Analgesic and Other Pain-Relief Drugs to Manage Chronic Low Back Pain: Results from a National Survey. *Pain Practice*. 2017; 17(3):353-365
14. <http://www.healthmeasures.net/explore-measurement-systems/promis>
15. Herndon C., Zoberi K., Gardner B., Common Questions About Chronic Low Back Pain. *American Family Physician* 2015; 91(10) 708-713 www.aafp.org/afp
16. Hoy D, et al. The Global Burden of Low Back Pain: Estimates from the Global Burden of Disease 2010 Study. *Ann Rheum Dis* 2014; 73:968–974. doi:10.1136/annrheumdis-2013-204428

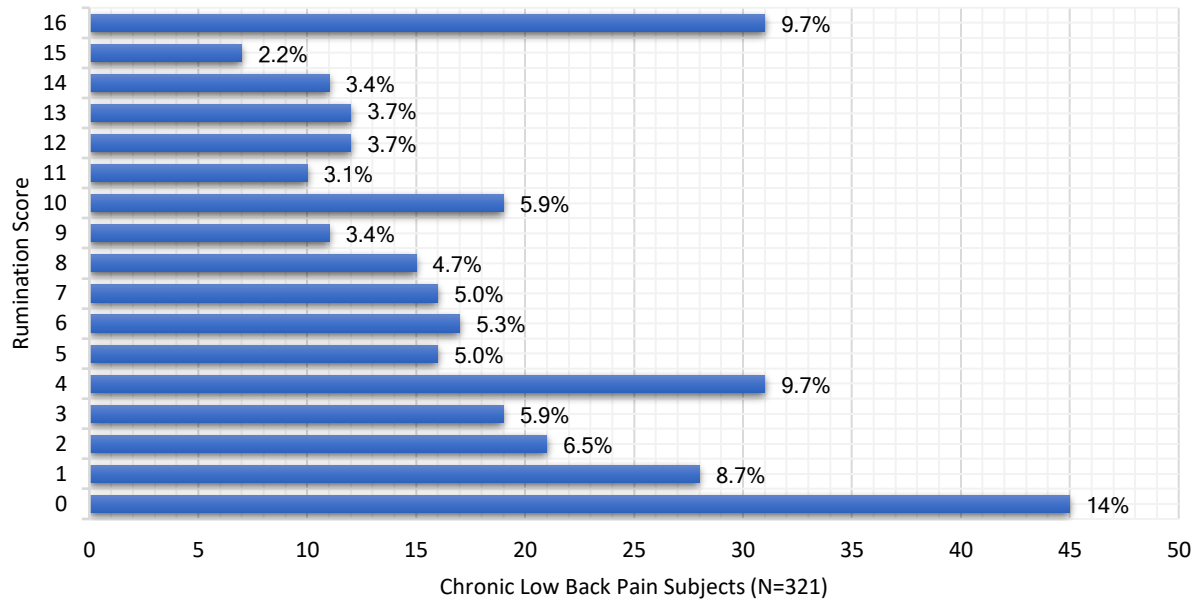
17. Interagency Pain Research Coordinating Committee. National pain strategy: a comprehensive population health-level strategy for pain. Washington, DC: US Department of Health and Human Services, National Institutes of Health; 2016
18. Jacobson P., Butler R. Relation of cognitive coping and catastrophizing to acute pain and analgesic use following breast cancer surgery. *J Behav Med* 1996; 19:17-29
19. Keefe F., Rumble M., Scipio C., et al. Psychological aspects of persistent pain: Current State of the Science. *The Journal of Pain* 2004; 5(4): 195-211. Doi: 10.1016/j.jpain.2004.02.576
20. Kovacs F.C., Seco, J., et al. The prognostic value of catastrophizing for predicting the clinical evolution of low back pain patients: a study in routine clinical practice within the Spanish National Health Service. *The Spine Journal*. 2012;12(7):545-555, <https://doi.org/10.1016/j.spinee.2012.06.002>.
21. Lethem J, Slade PD, Troup JDG, Bentley G. Outline of a fear avoidance model of exaggerated pain perception-I. *Behav Res Ther* 1983;21:401–408. [PubMed: 6626110]
22. Manchikanti L., Singh V., Falco F.J.E., et al. Epidemiology of Low Back Pain in Adults. *Neuromodulation* 2014; 17:3-10
23. Marhold C., Linton SJ., Melin L. Identification of obstacles for chronic pain patients return to work. Evaluation of a questionnaire. *J Occup Rehabil* 2002; 12: 65-75
24. Mayer TG, Gatchel RJ. Functional Restoration for Spinal Disorders: The Sports Medicine Approach. Philadelphia. Lea & Fehiger 1988
25. McCormack HM, Horne DJ, Sheather S. Clinical applications of visual analogue scales: a critical review. *Psychol Med* 1988;18:1007–19

26. Moore E., Thibault P., Adams H., Sullivan M., Catastrophizing and pain-related fear predict failure to maintain treatment gains following participation in a pain rehabilitation program. *Pain Reports* 1 2006; e567. Doi:10.1097/PR9.0000000000000567
27. Ogunlana, O.M., Odole, A.C., et al. Catastrophising, pain, and disability in patients with nonspecific low back pain. *Hong Kong Physiotherapy Journal*. 2015; 33: 73-79
28. Pulvers K, Hood A. The Role of Positive Traits and Pain Catastrophizing in Pain Perception. *Current pain and headache reports*. 2013;17(5):330. doi:10.1007/s11916-013-0330-2.
29. Roth R., Geisser M., Williams D. Interventional pain medicine. Retreat from the biopsychosocial model of pain. *TMB* 2012; 2:106-116 doi:10.1007/s13142-011-0090-7
30. Severijns R., Van den Hout M., et al. Pain catastrophizing and general health status in a large Dutch community sample. *Pain* 2002; 99:367-376
31. Sherwin L., Leary E., Henderson W. The association of catastrophizing with quality of life outcomes in patients with irritable bowel syndrome. *Qual Life Res* 2017; 26:2161-2170. Doi: 10.1007/s11136-017-1554-0
32. Stanton TR, Henschke N, Maher CG, et al. After an episode of acute low back pain, recurrence is unpredictable and not as common as previously thought. *Spine* 2008;**33**:2923–2928
33. Sullivan MJL., Adams H.,Martel M.,Scott W., Wildeman T. Catastrophizing and Perceived Injustice: Risk Factors for the Transition to Chronicity After Whiplash Injury. *Spine* 2011; 36(25s): s224-s249
34. Sullivan MJL, Pain Catastrophizing Scale User Manual. 2009. 1-36

35. Sullivan MJL, et al. Theoretical perspectives on the relation between catastrophizing and pain. *The Clinical Journal of Pain*. 2001; 17(1):52–64. [PubMed: 11289089]
36. Sullivan MJ, Rodgers WM, Wilson PM, Bell GJ, Murray TC., et al. An experimental investigation of the relation between catastrophizing and activity intolerance. *Pain* 2002; 100:47– 53.
37. Trost, Z. et Al Heritability of Pain Catastrophizing and Associations with Experimental Pain Outcomes: A Twin Study. *Pain*. 2015 March; 156(3): 514–520.
doi:10.1097/01.j.pain.0000460326.02891.fc.
38. Tsui P., Day M., Thorn B., et al. The Communal Coping Model of Catastrophizing: Patient- Health Provider Interactions. *Pain Medicine* 2012. 13:66-79
39. Turk D, Okifuji A. Psychological factors in chronic pain: Evolution and revolution. *Journal of Consulting and Clinical Psychology*. 2002; 70:678–690. [PubMed: 12090376]
40. Vallury KD, Jones M, Oosterbroek C. Computerized cognitive behavior therapy for anxiety and depression in rural areas: a systematic review. *J Med Internet Res*. 2015;17(6):e139.
41. Van der Windt D., Kuijpers T., Jellema P., et Al. Do psychological factors predict outcome in both low-back and shoulder pain? *Ann Rheum Dis* 2007; 66:313-319.
Doi10.1136/ard.2006.053553
42. Vitoula K., Venneria A., Varassi G., et al. Behavioral Therapy Approaches for the Management of Low Back Pain: An Up-To-Date Systemic Review. *Pain Ther* 2018 7:1-12. doi:10.1007/s40122-018-0099-4

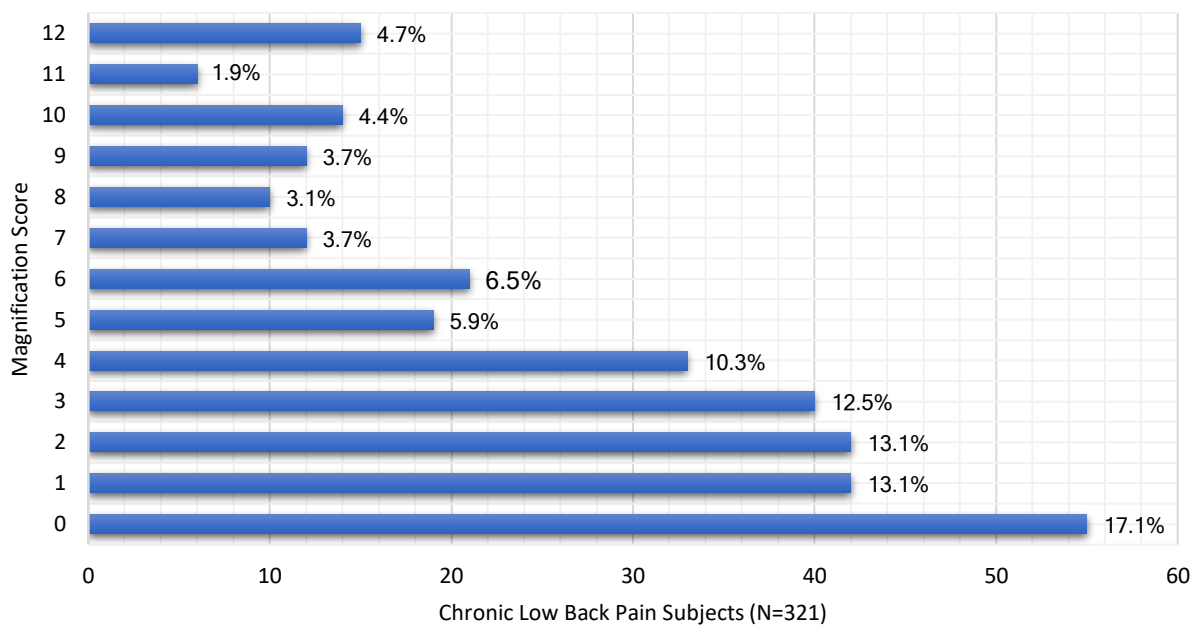
APPENDIX A: Supplemental Data

Figure 1: Frequency of PCS Scoring for Rumination
Among Total Sample



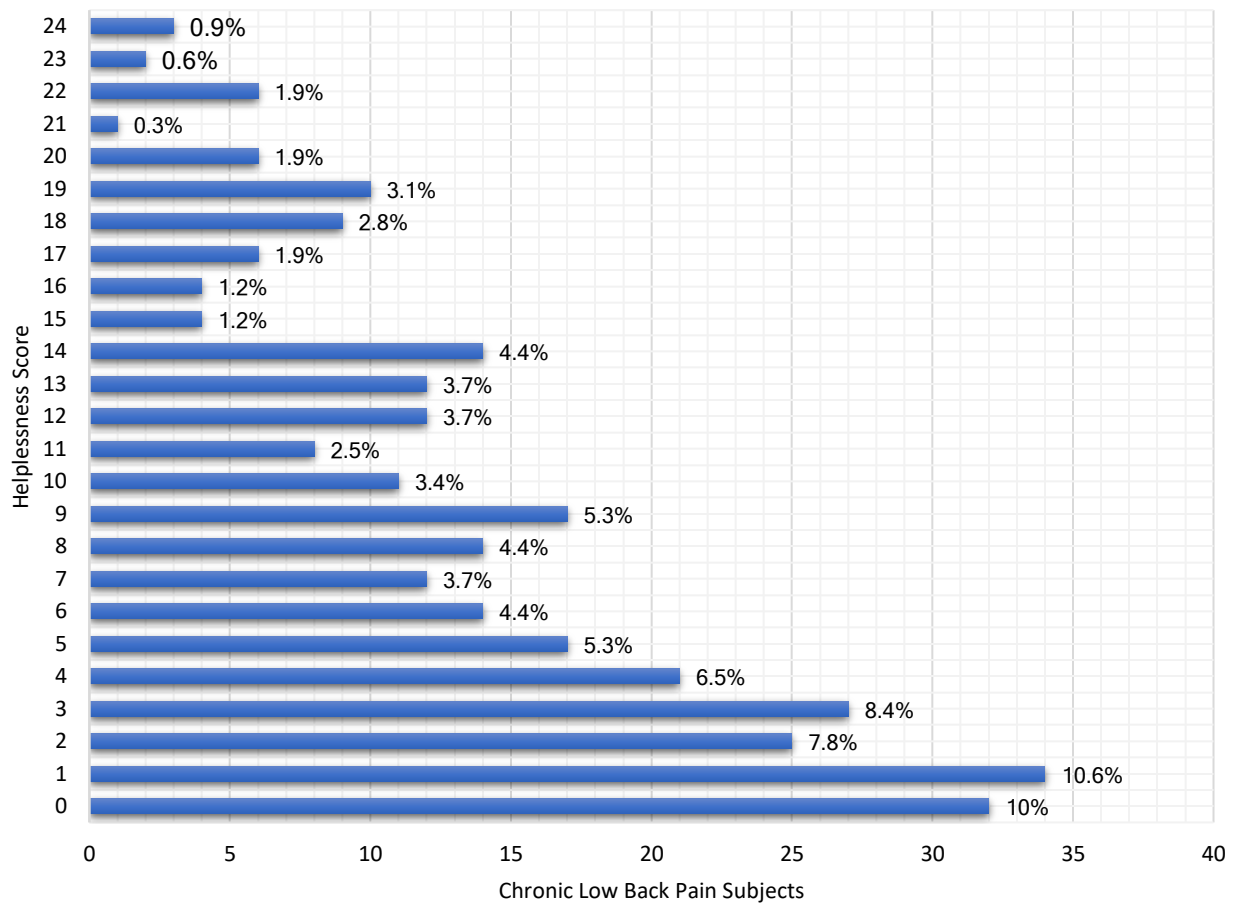
Scores range from 0-16 on a four-question series of the PCS questionnaire. Bars represent the number of LBP subjects (x-axis) that represented each score (Y-axis). Percent of total population that received each score is labeled next to corresponding bar.

Figure 2: Frequency of PCS Scoring for Magnification
Among Total Sample



Scores range from 0-12 on a three-question series of the PCS Questionnaire. Bars represent the number of LBP subjects (x-axis) that represented each score (Y-axis). Percent of total population that received each score is labeled next to corresponding bar.

Figure 3: Frequency of PCS Scoring for Helplessness
Among Total Sample



Scores range from 0-24 on a six-question series of the PCS Questionnaire. Bars represent the number of LBP subjects (x-axis) that represented each score (Y-axis). Percent of total population that received each score is labeled next to corresponding bar.

APPENDIX B: Questionnaires and Score Conversion

Pain Catastrophizing Scale Questionnaire

“We are interested in types of thoughts and feelings that you have when you are in pain. Listed below are thirteen statements describing different thoughts and feelings that may be associated with pain. Using the following scale, please indicate the degree to which you have these thoughts and feelings when you are experiencing pain.

0- Not at all	1- To a slight degree	2- To a moderate degree	3- To a great degree	4- All the time
---------------	-----------------------	-------------------------	----------------------	-----------------

1. I worry all the time about whether the pain will end.
2. I feel I can't go on.
3. It's terrible and I think it's never going to get any better.
4. It's awful and I feel that it overwhelms me.
5. I feel I can't stand it anymore.
6. I become afraid that the pain will get worst.
7. I keep thinking of other painful events.
8. I anxiously want the pain to go away.
9. I can't seem to keep it out of my mind.
10. I keep thinking about how much it hurts.
11. I keep thinking about how badly I want the pain to stop.
12. There is nothing I can do to reduce the intensity of the pain.
13. I wonder whether something serious may happen.”

Promis-29 Quality of Life Questionnaire for Depression

Depression In the past 7 days...	Never	Rarely	Sometimes	Often	Always
I felt worthless	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
I felt helpless.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
I felt depressed.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
I felt hopeless.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Table 11: Conversion of PROMIS-29 scores for depression.

PROMIS-29 Raw Score Conversion Table ¹³		
Raw Score	T-Score	SE*
4	41.0	6.2
5	49.0	3.2
6	51.8	2.7
7	53.9	2.4
8	55.7	2.3
9	57.3	2.3
10	58.9	2.3
11	60.5	2.3
12	62.2	2.3
13	63.9	2.3
14	65.7	2.3
15	67.5	2.3
16	69.4	2.3
17	71.2	2.4
18	73.3	2.4
19	75.7	2.6
20	79.4	2.6

***SE=Standard Error on T-Score**

T-score based on mean of general population reference sample. Normal T-score range 40-60 (Mean: 50 ±10)

APPENDIX C: IRB Forms

Study Protocol

University of North Texas Health Science Center

Office for the Protection of Human Subjects / Institutional Review Board (IRB)

Protocol Synopsis for Research Project Involving Human Subjects

PROTOCOL INFORMATION

Title of Research Activity: Pain Registry for Epidemiological, Clinical, and Interventional Studies in North Texas (PRECISION TEXAS)

Substudy: The Osteopathic Difference in Treating Patients with Low Back Pain (Funded by the American Osteopathic Association)

Name of Principal Investigator: John C. Licciardone, DO, MS, MBA

Names of each Co-Investigator: Robert J. Gatchel, PhD, Subhash Aryal, PhD, Jenny Lee, PhD, MPH, CHES, Nicole Phillips, PhD, David C. Mason, DO, MBA

Sponsoring Agency / Company (if applicable): Osteopathic Heritage Foundation/American Osteopathic Association

Sponsor's Grant Number: OHF - N/A; AOA - 131611703

IRB APPROVED

AUG 07 2018

A. OVERALL REGISTRY SPECIFIC AIMS –

**NORTH TEXAS REGIONAL IRB
UNT HEALTH SCIENCE CENTER**

Specific Aim 1: Develop a pain registry that will serve as a foundation for future research studies on subacute and chronic pain, particularly low back pain.

Specific Aim 2: Develop a biobank that will serve as a foundation for future research studies on low back pain.

Specific Aim 3: Conduct statistical analysis to determine the association between demographic, clinical and genetic variables and progression from subacute to chronic low back pain.

Specific Aim 4: Conduct statistical analysis to determine the association between demographic, clinical and genetic variables and recovery from chronic low back pain.

SUBSTUDY 1 SPECIFIC AIMS –

Specific Aim 1: Processes of medical care for low back pain. Are there differences in practice style between DOs and MDs that may be observed using patient-reported perceptions of their physician's communication style, empathy, and other dimensions of medical care, including OMT?

Specific Aim 2: Clinical outcomes of medical care for low back pain. Are there differences between DO and MD patients on reported measure of pain intensity and back-related functioning over 6 months?

Specific Aim 3: To study relationships between processes (Specific Aim1) and outcomes (Specific Aim 2) of medical care for low back pain.

B. BACKGROUND AND SIGNIFICANCE –

OVERVIEW OF LOW BACK PAIN

Low back pain is a common health condition in the United States of America that causes considerable time lost from work, decreased quality of life and disability.

According to the 2011 *Institute of Medicine Report, Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research*, more than 100 million Americans suffer from chronic pain, and a conservative annual estimate of the cost of chronic pain to the US economy is \$560-635 billion.

Chronic pain, including low back pain, continues to be a focal area of interest of the National Institutes of Health – National Center for Complementary and Integrative Health. Thus, this research registry project and the foundation it will provide for future studies is very timely and fits well in the national pain research landscape.

C. PRELIMINARY STUDIES –

Not applicable

D. INVESTIGATOR EXPERIENCE –

Dr. Licciardone's education, medical training, and previous experience in conducting a wide range of research studies have prepared him to serve as principal investigator for this research registry. He previously completed four randomized controlled trials involving OMT, including two in the area of nonspecific chronic low back pain. The OSTEOPATHIC Trial has been described as a "large, high quality clinical trial" ... that "set a major milestone in the osteopathic field." Additionally, his research team's published clinical trial report in the *American Journal of Obstetrics and Gynecology* (2010) was the first to signal improvements in back-specific functioning with any type of manual treatment in women during the third trimester of pregnancy. It was recognized in NIH-NCCIH's Research Spotlight. Dr. Licciardone's systematic review and meta-analysis of OMT for low back pain, published in *BMC Musculoskeletal Disorders* (2005), is the basis for osteopathic medicine's only clinical practice guideline, which has been accepted by the Agency for Healthcare Research and Quality on its National Guideline Clearinghouse. His previous research on low back pain has been recognized by such entities as the World Health Organization (serving as a consultant on international regulatory and safety issues relating to osteopathy), the National Institutes of Health – National Center for Complementary and Integrative Health (serving as an expert panelist for their Workshop on Deconstructing Back Pain), and the Interagency Pain Research Coordinating Committee (serving as a member of the Federal Pain Research Strategy Working Group from 2016 to present). Numerous organizations have asked him to speak at national and international conferences.

To date, he has published over 100 papers. A partial list of these publications, is provided in the curriculum vitae on file with the original IRB application for this study.

E. EXPERIMENTAL DESIGN AND METHODS –

1) Methods and Procedures:

Potential subjects recruited for this registry will be asked to complete up to five encounters with the UNT Health Science Center during the first 12 months to provide data relative to their experience with low back pain. The research team will collect data on physical, emotional and social aspects of low back pain, medications and other treatments for low back pain, characteristics of physicians who provide low back pain care, and genetic and biomarker samples at the baseline visit. While the initial baseline

visit must be conducted in person in order to execute informed consent, confirm age and identity, collect information needed to process compensation, and collect biological samples. Subsequent study encounters at 3 months, 6 months, 9 months, and 12 months of enrollment in the registry may be completed in-person, by telephone or online. Subjects will be asked to provide an email address as part of the contact information gathered from each person enrolled in the study. Participants will receive compensation for each of the five encounters during the first 12 months of the registry as long as they provide all information requested at the encounter. Because this is a research registry, members of the research team plan to follow-up beyond the initial 12-month active period on a quarterly basis for an indefinite period of time.

Beginning at 15 months post enrollment, subjects will be contacted by phone or email to initiate completion of quarterly follow-up surveys. These encounters will be conducted primarily by phone or online as compensation will be reduced to \$10 per encounter. If a subject prefers to complete the encounter in-person, a visit will be scheduled. Based on staffing levels and research space constraints, subjects will be encouraged to complete surveys 15 months plus post enrollment remotely. Compensation will be provided for each encounter as outlined in the compensation schedule on page 9. This survey instrument will be used for quarterly encounters at 15, 18, 21, 27, 30, 33, 36, 39, 42 and 45 months post-enrollment.

At 24 months and 48 months post-enrollment, subjects will be asked to complete a longer survey that includes questions about pain perception, medications taken for other medical conditions and drug adverse events. Items from the baseline survey will also be included. Compensation for the 24-month and 48-month encounters will be \$25.

Subjects will be compensated using a web-based payment system (such as Greenphire), which will offer flexibility in spending the compensation, as well as streamline the compensation process and enhance the payment reporting structure. The web-based payment system is HIPAA-compliant, and only the appropriate key personnel have access to subjects' personal identifiable information stored in the system. Study key personnel will explain the compensation process thoroughly to each subject and will provide specific information (FAQ approved by the IRB) to each subject on how to access the compensation. The FAQ will be provided with the consent document so subjects understand how the compensation process works prior to signing consent. The FAQ will be provided with the consent regardless of whether the subject re-consents in person, by mail or by email.

Compensation will be reported and taxed in accordance with institutional, state and federal guidelines.

Please note that as we transition to the web-based payment system, we intend to disburse the remaining physical and electronic gift cards in our possession. During this transition, subjects will be offered a choice of being compensated through the web-based system or of receiving a physical or electronic retail gift card. Since there will be a limited number of gift cards available, they will be disbursed on a first-come, first-served basis until the supply is exhausted. Once all current physical and electronic gift cards are disbursed, all payments will be made through the web-based system. If a subject chooses not to complete the W-9 form, he or she may still choose to participate in the study but will not be compensated for participation. This is clearly explained in the consent document.

Every active subject will be asked to sign a new consent form detailing the change in payment method. The re-consent process will be mentioned to subjects as they are scheduled for their next quarterly visit. Subjects will then have the option to schedule an in-person visit to complete the new consent document in conjunction with their quarterly visit. In lieu of an in-person visit, subjects may choose to receive the re-consent by email to sign and scan back to study personnel. They may also elect to receive the consent document via the U.S. Postal Service and return the signed consent and W-9 form using an enclosed business reply envelope. Please note that all initial consent documents will be executed in-person, and that only re-consent documents may be completed via email or mail. This gives study personnel a signature on file to confirm that the person signing the re-consent is using a comparable signature to the original consent. Subjects may return the completed and signed W-9 form in the same

manner as outlined for the consent document. All documents returned via mail will be sent in a business reply envelope that is sent directly to the attention of Ms. Kearns, which ensures only key personnel open mail that may contain social security numbers. Security envelopes will be used so that the information enclosed in the envelopes cannot be seen while in transit. Subjects who are re-consenting remotely will be instructed to call the study coordinators if they have any questions about the consent document or compensation. Once the subject has completed the re-consent process, he/she will be registered in the web-based payment system and the sealed card packet containing the card and a cardholder agreement will be sent to the subject. Please note that the card does not have any value until funds are loaded following completion of an encounter.

The web-based system also allows subjects to opt-in to appointment reminders and compensation confirmation by email and text message. If subjects choose to receive text messages from the automated system, standard text messaging rates will apply.

Two other items to note: 1). Subjects do not interact with the web-based payment vendor. Study personnel register the subject and approve all payments. Subjects interact only with MasterCard customer support. 2). A concern was raised that subjects could potentially complete surveys without being re-consented. Study personnel send a survey link for each encounter and no survey link will be sent unless the subject has signed and returned the re-consent document and the completed W-9.

The SA Form is the baseline survey. The S3 form will be used at 3, 6, 9, and 12-month follow-ups. The S15 form will be used at the 15-month, 18-month, 21-month, 27-month, 30-month, 33-month, 36-month, 39-month, 42-month and 45-month encounters. The S24 form will be used the 24-month and 48-month encounters.

For all encounters beyond the baseline, phone encounters are being offered as some subjects currently enrolled in the study are not comfortable using the computer. Study coordinators are currently reading to these subjects during in-person visits and marking the answers in the Qualtrics survey on the subjects' behalf. This process can easily be converted to a phone interview to collect the data. These quarterly follow-ups will continue indefinitely.

For all encounters, the study coordinator will provide the subject with the unique identifying (subject ID) number that is requested in each survey after the screening questionnaire.

Following an in-person, phone, or online screening questionnaire (SQ Form) to ensure preliminary qualification for the registry, the participant will attend a baseline visit at the UNT Health Science Center Patient Care Center. The SQ form replaces the previously approved phone screening form. Prospective subjects who learn about the study through paper flyers or other means within the community may still call in to screen, and the online screening form will be read to them and completed by study personnel. In-person screenings may also be conducted using mobile devices such as a smart phone, tablet, or laptop computer. The online screening questionnaire is programmed to determine if a prospective subject passes or fails the screening based on responses to the questions. Prospective subjects receive immediate feedback after completing the screening, and those who are eligible for the registry are asked to provide contact information so that research personnel may contact them to complete the enrollment process and schedule a baseline visit. Prospective subjects will be told via instructions included in the online screening tool that they must attend the first study visit in-person, and that their responses to the screening questionnaire will be retained. We will ask for contact information from prospective subjects regardless of whether they pass or fail the screening. Contact information will be labelled as required for those who pass the screening in order to continue with the enrollment process; however, they may exit the questionnaire without providing such contact information if they elect to not pursue enrollment in the registry. Contact information will be labelled as optional for prospective subjects who fail the screen. If those individuals provide contact information, they are told that we may contact them at a later date to reassess eligibility for this research registry or for future research projects. If any prospective subject starts the online screening questionnaire and exits prior to providing contact information, no personal identifiable information is

stored in Qualtrics. Thus, identifiable information (contact information) will be retained for all people who pass the screening for the research registry and provide such information, and for those who fail the registry screening, but who remain interested in future study participation and submit contact information. Both scenarios are clearly noted in the instructions for completing the screening questionnaire form. A script will be used when following up with prospective subjects who passed the screening online.

The baseline visit will be scheduled as soon as feasible given available appointments, ideally within two to three weeks of the participant passing the screening. At the baseline visit, the potential subject will complete informed consent prior to responding to any data collection instruments or providing the genetic and biomarker samples. Once informed consent has been executed, subjects will be asked to complete a series of questions related to their low back pain and how it impacts their life.

These questions are primarily drawn from the following:

- NIH minimum dataset for chronic low back pain (Deyo, et al, 2014);
- PROMIS Quality of Life Measures (PROMIS, 2015)
- Roland-Morris Disability Questionnaire (Roland and Morris, 1983)
- Pain Catastrophizing Scale (Sullivan, et al, 1995)
- Pain Self-Efficacy Scale Questionnaire (Nicholas, et al, 2007)
- Several items related to medications used and treatments received for low back pain
- Items related to diagnosed medical comorbidities
- Communicable Behavior Questionnaire (Farin, et al, 2012)
- Consultation and Relational Empathy Measure (Mercer, et al, 2004)
- Jefferson Scale of Physician Empathy (Kane, et al, 2007)
- Patient Satisfaction Questionnaire (Marshall and Hays, 1994)
- Jefferson Patient Satisfaction Measure (Hojat, et al, 2011)

Each subject will be asked to complete these questions using a computer or mobile device made available by project personnel. If the subject has difficulty seeing the screen, using the computer/mobile device, or reading the questions, the research coordinator will assist the subject in completing the questionnaires. Subjects may complete the questionnaire on paper if it cannot be completed electronically. The electronic survey permits subjects to take breaks while answering the questions if needed. Each subject will be assigned a unique identifying number that will be used to store that person's responses in Qualtrics. No personal identifying information will be stored in Qualtrics. The master file with the subject's name, contact information and identifying number will be kept in a separate, password-protected document. The consent will be executed using a paper document. All signed consent documents, copies of any data questionnaires, and copies of any other IRB-approved forms deemed necessary by study personnel completed in paper format will be maintained in a locked file cabinet in a secured space. A copy of each questionnaire will be maintained electronically by the subject's unique identifying number as a backup to the external data system managed by Qualtrics. These PDF copies will be stored in a password-protected area. Digital copies of other study forms may be maintained as deemed necessary by study personnel. All digital documents will be stored in a password protected area. Only the appropriate authorized key personnel will have access to the consent documents and other study documents.

At the baseline visit, subjects will also be asked to provide a saliva sample for genetic analysis. The saliva sample will be delivered to the genetics facility in the Center for BioHealth, where it will be stored and analyzed. All genetic samples will be coded with a unique identifying number and a barcode on the tube containing the sample. Laboratory personnel will not have access to personal identifiable data for any subjects.

At the baseline visit, certified phlebotomists will draw up to 30 ml (approximately two tablespoons) of blood for biochemical and genetic analysis. Blood samples will be marked with a unique identifier and transported to the genetics facility in the Center for BioHealth. If for some reason the blood cannot be

drawn at the baseline visit, it will be drawn at a subsequent follow-up visit. No personal identifiable information will be stored with the blood sample.

Genetic samples, biomarker samples and responses to registry questionnaires will be used for analyses as indicated in the specific aims for the initial phase of this registry project and for the substudy as indicated. They will also be analyzed in future studies related to low back pain and other conditions related to pain.

Potential subjects will be asked to bring an original, valid, government-issued photo identification to confirm identity and age at the baseline visit. They will also be asked to bring the medications they take for low back pain, or provide a list of those medications. If potential subjects do not bring an original, valid identification or provide the medications, they will not be enrolled in the study or compensated for time and travel until they provide the requested information at a rescheduled visit. If a subject reports not taking any medication for low back pain at the baseline visit, the subject will be asked to sign a form verifying this information. Because a potential subject does not need to be taking medication for low back pain to enroll in the study, the signed form confirming this information will serve as adequate documentation for enrollment in the study. Please note that the baseline visit will only be rescheduled once because of missing documentation. If the potential subject arrives the second time without the requested information, the individual will not receive any compensation, and he/she will not be enrolled in the study.

All compensation will be documented in compliance with institutional policies.

Recognizing that some subjects rely on receiving compensation at the time of in-person visits to pay for gasoline to travel home, and not wanting to create undue hardship for subjects or prospective subjects, a one-time payment of \$10 may be provided if the subject arrives for the baseline visit without the photo identification or medications/medication list. Because this would be a one-time payment (i.e., could only occur at one visit), the subject would still receive the amount of compensation designated for that visit once the requested information is provided and documented in the subject's research chart. The \$10 payment may also be used at the baseline visit if the potential subject chooses to take the consent form home to review with family members prior to executing informed consent, or if study personnel feel the prospective subject is unable to execute informed consent for any reason.

Occasionally, study personnel may need to contact registry participants between study encounters to clarify study-related data.

Subjects may be invited to participate in other future research projects based on specific information provided during the initial phase of the research registry. Subsets of participants may be invited based on the specific aims and inclusion/exclusion criteria for future studies. Future studies will not be pursued without express approval from the IRB. A re-contact clause is included in the informed consent document. Contact would be made by the subject's preferred method of communication as noted on the most recent contact update form. Subjects may choose more than one preferred method of communication, and each of those methods may be used.

Additional Study Population – Control Subjects (Study Population 2)

Data collection for up to 1,000 control subjects will be gathered through an in-person visit to the UNT Health Science Center Campus. These control subjects will be recruited using the same venues as subjects with low back pain. They will complete the screening form CON-SQ online, by phone or in-person.

During this visit, control subjects will complete the CON-Baseline survey. Study personnel will also collect saliva and blood samples as outlined in this protocol for subjects. The control subjects will be compared to subjects with low back pain on self-reported measures, genetic measures and biomarker measures.

Control subjects will be compensated \$50 for this visit using a web-based payment system (Such as Greenphire). Just as with subjects, each control subject will be asked to complete a W-9 form that will be maintained in their study chart.

Subjects will not specifically be told that they are control subjects. They will be recruited to a health status study.

Inclusion Criteria for Control Subjects (Study Population 2)

- 21 years-of-age to 79 years-of-age (documented by an original, valid, government issued photo identification at baseline visit)
- Report not having pain in any area of their body at least half or more than half the days of the past two months
- Able to understand informed consent
- Speak and respond to questions asked in English as no translation services will be available
- Provide information about medications taken (self-report only)
- Must report having a physician, must be able to tell study staff if physician is a MD or DO, and must report having this physician for a period of at least one to three months

Exclusion Criteria for Control Subjects (Study Population 2)

Control subjects must not be:

- Pregnant (self-report only)
- Incarcerated or institutionalized

Please note there is a separate screening form for control subjects (CON-SQ), a separate baseline screening survey (CON-Baseline), a separate consent (Version C-1), separate advertisements (Health Status – Tell Us About Your Health), and a separate form for subject tracking and subject contact flow sheet. All documents are marked HEALTH STATUS instead of PRECISION TEXAS. Subject recontact clauses, data storage and confidentiality, compensation, genetic analysis and biomarkers, and other study processes will be handled as outlined in this protocol for subjects with low back pain.

Substudy 1 Protocol Change for Subjects 1-51 Only:

Data collected for the substudy includes asking subjects several questions related to their relationship with the physician who treats them for their low back pain. Questions focus on physician communication styles, empathy and patient satisfaction with care. Use of these questions was previously approved by the IRB under this protocol and were added to the baseline survey beginning with subject number 52. We would like to collect this same information for subjects 1-51. A separate consent (AOA Substudy Consent) would be completed by each subject at her or his next quarterly visit. The subject would then be asked to complete the online survey (Form AOA1) in addition to the survey for that visit. Subjects would not receive any additional compensation for completing this survey as the anticipated completion time is approximately 10-15 minutes. Please note that there is a separate consent for this substudy.

Please note this substudy survey has been completed as outlined above and is no longer in use as of February 2018.

Inclusion Criteria (Study Population 1)

To participate in the registry, subjects must be:

- 21 years-of-age to 79 years-of-age (documented by an original, valid, government issued photo identification at baseline visit)
- Report having low back pain for at least two months; **AND** report having low back pain for at

- least half of the days for the past two months
- Able to understand informed consent
- Speak and respond to questions asked in English as no translation services will be available
- Provide information about medications taken for low back pain (self-report only)
- Must report having a physician, must be able to tell study staff if physician is a MD or DO, and must report having this physician for a period of at least one to three months

Exclusion Criteria (Study Population 1)

To enroll in the registry, subjects must not be:

- Pregnant (self-report only)
- Incarcerated or institutionalized

Women who report being pregnant during the screening or at the baseline visit will not be considered eligible to enroll in the registry, however, a woman who reports being pregnant after enrolling in the registry will be permitted to remain in the registry.

A detailed explanation of laboratory analysis for the genetic samples and data confidentiality are included in the appropriate sections below.

Participants may withdraw from the registry at any time and, upon written request to the PI, may ask to have their data, and genetic and biomarker samples discarded. Subjects may also ask that they not be contacted further, but may choose to allow the research team to continue to use data provided up to that point and to continue to use the genetic/biomarker samples and corresponding data. Both of these options are clearly described in the main informed consent document for the registry.

2) Data Analysis and Data Monitoring:

Statistical analyses will be performed for the baseline and follow-up surveys, as well as for the genetic and biomarker data. Demographic, clinical, and relevant genetic/biomarker data will be merged to facilitate analyses of the primary hypotheses outlined herein. These analyses may include basic descriptive statistics as well as analytical statistics to assess the primary hypotheses and other secondary hypotheses as indicated by the data.

3) Data Storage and Confidentiality:

Data collected through Qualtrics will be stored in the cloud service operated by Qualtrics, and will periodically be downloaded into an SPSS database. Since each subject will be assigned a unique identifying number, research data will be stored separately from personal identifiable information. All data downloaded from Qualtrics will be kept on computer hard drives, external hard drives, or secure servers in password-protected files. PDF copies of each subject survey will also be downloaded from Qualtrics and will be kept in a password-protected area. Only the appropriate key personnel will have access to these password-protected files.

Members of the research team may print a copy of the subject's survey prior to submission for the first several subjects until the team is confident that data is reliably porting to Qualtrics following implementation of new or revised study forms. If at any time, there is a problem with survey responses loading into the Qualtrics database, with the computer, or with internet access, the team may revert to printing surveys or using paper surveys until the issue is resolved. Any printed documents will be maintained in that subject's paper research chart along with the phone screening, signed informed consent and other research documents. The paper files will be maintained in a locked file cabinet in a secure space.

Personal identifiable information will be kept in password-protected master file by study key

personnel. The password-protected file will be backed up to an external hard drive or secure server to ensure data redundancy in the event of equipment failure.

Any paper consent or other data collection forms completed on paper will be stored in a locked file cabinet in a secure space.

Genetic and biomarker samples will be stored at temperatures of minus 20 degrees Celsius while they are being used for various processes short-term. Long-term, samples will be stored in a minus 80 degrees Celsius freezer. The secure freezer is housed in the genetics facility. Only authorized key personnel will have access to the samples from registry participants. Saliva samples will be collected using ORAGENE Discover collection vials. One vial will be collected per subject, and the vial will be identified with a barcode that corresponds to the subject's unique identifying number. Once the sample is processed for long-term storage, that tube will be identified using a label with the same barcode used on the collection vial.

Blood will be collected as outlined above and transported to the genetics facility in the Center for BioHealth, where trained key personnel will centrifuge the blood and separate it into serum, plasma and the buffy coat. A portion of each subject's blood sample will be stored as whole blood. These samples will be stored in the secured freezer until they are processed. All procedures will be completed in accordance with the institution's biosafety policy.

Genetic data will be stored on a stand-alone computer in the genetics facility in the Center for BioHealth. All genetic data will be kept by the unique identifying number assigned to each subject, and will be stored in a password-protected file. Because personnel in this work group are accustomed to working with genetic data for criminal cases, they are trained to follow security requirements set forth by the Federal Bureau of Investigation. Only authorized key personnel will have access to genetic data.

Because genetic information will eventually be derived from this registry, we intend to seek a certificate of confidentiality from the National Institutes of Health to offer an additional layer of protection of our participants' privacy and confidentiality.

Biomarker data will be stored on a secured computer in the department. All data will be assigned a unique number, and will not be stored with personal identifying information.

All potentially clinically-relevant genetic data are generated for research purposes only, and will not be provided to the participants or their healthcare provider.

4) Setting:

In the first 12 months, when a subject is enrolled in the research registry, the first encounter will be conducted in-person at the UNT Health Science Center Patient Care Center. The remaining four encounters in the first year of enrollment may be conducted in-person at the UNT Health Science Center campus, or the encounters may be completed by phone or online as described earlier in this protocol synopsis. All 15-month post-enrollment and subsequent encounters will be conducted by phone, online or in-person, with preference given to phone and online visits.

5) Laboratory Methods and Facilities:

Saliva samples for genetic analysis will be processed for long-term storage and stored in the genetics facility in the Center for BioHealth. These samples will be collected using ORAGENE Discover collection vial for collection and stabilization of saliva samples. Collection vials for saliva and blood, as well as any subsequent sample storage tubes will be coded with a personal unique identification number to protect confidentiality of the genetic and biomarker data.

DNA will be extracted from samples using automated and manual extraction methods appropriate for

the sample types. DNA samples will be quantified to determine the amount of nuclear or mitochondrial DNA. Portions of the DNA obtained from the various sample types will be amplified using the polymerase chain reaction for DNA sequence data, autosomal, Y chromosomal, mitochondrial DNA, insertions, deletions, and other SNP DNA markers under development for genetic analysis. These methods include but are not limited to DNA sequencing, autosomal STR typing using commercially available STR typing kits, or in-house designed STR assays and genetic typing with new SNPs and or insertion/deletion panels. SNP testing will include markers within genes that affect drug metabolism and genotypes at these loci. This information, along with data on copy number variation of relevant genes, will be used to infer individual metabolizer status of commonly used pharmaceuticals based on published literature and validated guidelines from the Clinical Pharmacogenetics Implementation Consortium (CPIC). DNA fragments and sequence data may be visualized by capillary electrophoresis using an Applied Biosystems 3130xl and/or 3500xl Genetic Analyzer (Applied Biosystems, Foster City, CA), real-time PCR using an Applied Biosystems 7300/7500, or other relevant techniques. Mitochondrial haplotype data will be compiled and analyzed using the GeneCodes Sequencer™ 4.7 software. Autosomal and Y STR data will be compiled and analyzed using either the Applied Biosystems GeneMapper ID software or in-house developed software. Genetic data will be maintained in electronic format on password protected secure computers or servers maintained in the genetics facility. The data will only be shared with authorized key personnel via a secure file sharing service or FTP site.

Any and all of the biological samples collected or data generated from this registry may be used in future studies to evaluate, compare, and validate technologies for DNA extraction, phenotypic traits, repair, WGA, amplification, typing, sequencing, purification, robotics, expert systems, Laboratory Information Management Systems and other genetic analysis techniques. Routine laboratory procedures may be performed by offsite contractors provided the samples are de-identified prior to the work being performed. Archived saliva samples and isolated DNA will be stored indefinitely or until exhausted.

6) Estimated Period of Time to Complete the Study (Study Population 1):

Encounter	Tasks	Estimated Time to Complete	Compensation
Baseline	Execute informed consent; provide photo id; complete baseline Qualtrics survey (Form SA); provide saliva sample for genetics analysis and blood for biochemical and/or genetic analysis; obtain information about low back pain medications. Visit must be completed in person.	Up to 3 hours	\$50
Month 3	Update contact information; complete follow-up Qualtrics survey (Form S3); obtain information about low back pain medications. Encounter may be completed in person, by phone or online.	30 minutes to 1 hour	\$25
Month 6	Update contact information; complete follow-up Qualtrics survey (Form S3); obtain information about low back pain medications. Encounter may be completed in person, by phone or online.	30 minutes to 1 hour	\$25
Month 9	Update contact information; complete follow-up Qualtrics survey (Form S3); obtain information about low back pain medications. Encounter may be completed in person, by phone or online.	30 minutes to 1 hour	\$25
Month 12	Update contact information; complete follow-up Qualtrics survey (Form S3); obtain information about low back pain medications. Encounter may be completed in person, by phone or online.	30 minutes to 1 hour	\$25
Months 15, 18, 21, 27,	Update contact information; complete follow-up Qualtrics survey (Form S15). Encounters may be completed by	15-20 minutes	\$10

30, 33, 36, 39, 42 and 45 quarterly follow-up encounters	phone or online, or in-person.		
Months 24 and 48 quarterly follow-up encounters	Update contact information; complete follow-up Qualtrics survey (Form S24). Encounters may be completed by phone or online, or in-person.	30 minutes to 1 hour	\$25

Estimated Period of Time to Complete the Study (Study Population 2):

Encounter	Tasks	Estimated Time to Complete	Compensation
Baseline	Execute informed consent; provide photo id; complete baseline Qualtrics survey (Form CON-Baseline); provide saliva sample for genetics analysis and blood for biochemical and/or genetic analysis. Visit must be completed in person.	Up to 3 hours	\$50

F. HUMAN SUBJECTS –

1) Description of Subjects:

We intend to recruit up to 2,000 subjects (1,000 subjects with low back pain and 1,000 control subjects) for this registry project.

We plan to recruit participants 21 years-of-age to 79 years-of-age from the UNT Health Science Center clinics and from the Dallas-Fort Worth Metroplex using such methods as flyers, community events and venues, social media, electronic communications such as email, websites, online advertising, newspapers and other media outlets, and referrals from local physicians.

Women who report being pregnant during the screening process will not be considered eligible to enroll in the registry, however, a woman who reports being pregnant after enrollment will be permitted to remain in the registry.

We aim to recruit a racially and ethnically diverse group of subjects that generally follows the demographics reported for Tarrant County in the most recent United States census. Please see targeted enrollment table below for a specific breakdown.

We do not intend to recruit from vulnerable populations.

2) Sample Size:

Up to 2,000 subjects (1,000 subjects with low back pain and 1,000 control subjects) will be enrolled in the initial phase of this registry.

3) Describe both Inclusion / Exclusion Criteria:

Inclusion Criteria for Subjects with Low Back Pain (Study Population 1)

To participate in the registry, subjects must be:

- 21 years of age to 79 years-of-age (documented by an original, valid, government-issued photo identification at baseline visit)
- Report having low back pain for at least two months; **AND** report having low back pain for at least half of the days in the past two months
- Able to understand informed consent
- Speak and respond to questions asked in English as no translation services will be available
- Provide information about medications taken for low back pain (self-report only)
- Must report having a physician, must be able to tell study staff if physician is a MD or DO, and must report having this physician for a period of at least one to three months

Exclusion Criteria for Subjects with Low Back Pain (Study Population 1)

To enroll in the registry, subjects must not be:

- Pregnant (self-report only)
- Incarcerated or institutionalized

Inclusion Criteria for Control Subjects (Study Population 2):

- 21 years-of-age to 79 years-of-age (documented by an original, valid, government issued photo identification at baseline visit)
- Report not having pain in any area of their body at least half or more than half the days of the past two months
- Able to understand informed consent
- Speak and respond to questions asked in English as no translation services will be available
- Provide information about medications taken (self-report only)
- Must report having a physician, must be able to tell study staff if physician is a MD or DO, and must report having this physician for a period of at least one to three months

Exclusion Criteria for Control Subjects (Study Population 2)

Control subjects must not be:

- Pregnant (self-report only)
- Incarcerated or institutionalized

Minors under the age of 21 will not be included as low back pain is not prevalent in this population and clinical guidelines for pediatric patients should be based exclusively on pediatric populations. Pregnant women will not be enrolled in the registry if they report being pregnant at the time of screening as their back pain may be self-limiting based on physiological changes during the pregnancy. Women who report being pregnant after enrollment will be permitted to remain in the registry. People over 79-years-of-age will not be enrolled to help protect their identity within aggregated data sets. If enrolled, the relatively small number of such older subjects may potentially enable research staff to identify them based on their age and unmask their research data. However, enrolled patients will not be disenrolled after reaching 79 years of age.

We do not intend to recruit from vulnerable populations.

- 4) **Describe intended gender, age range, and intended racial and ethnic distribution for subjects with low back pain and control subjects:**

Race/Ethnicity	Targeted Enrollment
African American (Black)	318
American Indian / Native American	18
Asian	100
Caucasian (White)	1,002
Hispanic (Latino)	552
Native Hawaiian / Pacific Islander	4
Other /Unknown	6
Gender	Targeted Enrollment
Female	1,020
Male	980

The age range of participants for this registry includes adults age 21-years-old to 79-years-old at the time of enrollment.

- 5) **Identify the source(s) from which you will obtain your study population:**

Participants may be recruited from the UNT Health Science Center clinics and from the Dallas-Fort Worth Metroplex using such methods as flyers, newspapers and other media outlets, community events and venues, social media, electronic communications such as email, websites and online advertising, and referrals from local physicians. We plan to use a broad-based approach to recruiting subjects for this registry.

- 6) **Describe Plans for Recruitment of Subjects:**

We intend to recruit up to 2,000 subjects (1,000 subjects with low back pain and 1,000 control subjects) using UNT Health Science Center clinics, clinics throughout the Dallas-Fort Worth Metroplex, and the methods outlined herein.

In addition to posting flyers in the waiting area of clinics, study personnel may approach people in the waiting room, briefly describe the research registry and offer the person a flyer with study information to share with friends and family. Study personnel would not be asking for any personal health information, nor would they be asking if that individual had low back pain. Study personnel would seek approval from the clinic manager prior to employing this strategy.

We plan to seek referrals to the registry from physicians throughout the Metroplex using written correspondence, digital correspondence, telephonic communication, advertisements, and social media. We plan to recruit directly from the community using a broad approach including having a presence at community events and venues, developing events such as town hall meetings where community members are invited to the UNT Health Science Center campus, posting and advertising on social media, advertising on websites, running newspaper and other media advertisements, and broadly distributing flyers in a wide range of venues throughout the DFW area. Recruitment efforts

may also be informed by future recommendations made by members of the PRECISION TEXAS Community Advisory Board.

G. RISK/BENEFIT ANALYSIS –

1) Level of Risk / Description of Benefit:

The level of risk to participants in this registry is a minor increase over minimal risk. There is no direct benefit to participants recruited for this registry.

2) Describe How the Anticipated Benefit Justifies the Risk:

The risk to participants in this registry is a minor increase over minimal risk. There is no direct benefit to participants in registry. However, the study may lead to a better understanding of the natural progression of low back pain and, potentially, toward better targeting of treatments in the future.

3) Describe how the anticipated benefit of this research is at least as favorable to the subjects as that to be received by available alternative approaches for the subjects:

There are no interventions because this is a research registry project. However, future benefits may include developing a better understanding of the natural course of low back pain, which may lead to better or more personally targeted treatments.

4) Describe any potential RISKS OR DISCOMFORTS in detail. Use evidence from clinical and/or animal studies to evaluate the level of potential hazards associated with participation in the research protocol. Indicate the methods for detecting adverse reactions. Describe the procedures for protecting against or minimizing potential risks (e.g., confidentiality, reputational injury, direct injury or harm to subject, etc.) and assess their effectiveness. Discuss why the risks to the subjects are reasonable in relation to proposed benefits to mankind. Be sure to describe any anticipated adverse events that might occur during the course of the study.

A risk to subjects in this registry may be a potential loss of confidentiality if their genetic data is requested by the judicial system or by an insurer. In addition to the data safeguards in place, we intend to seek a certificate of confidentiality to prevent us from being required to disclose such genetic data to outside agencies or parties once such data is generated in our study.

Subjects may also experience embarrassment if they are unable to read or complete the forms on computer or mobile device. The research coordinator will be very sensitive to subjects who need assistance in order to alleviate any embarrassment.

Subjects may experience bruising or soreness at the site of the blood draw. Occasionally, a subject may feel lightheaded during or after a blood draw. Certified laboratory phlebotomists will be drawing the blood, and are trained to address these issues.

H. PAYMENT/COMPENSATION –

Subjects with low back pain (Study Population 1) will receive compensation for time and travel as follows: Baseline visit - \$50; Month 3 encounter - \$25; Month 6 encounter - \$25; Month 9 encounter - \$25; Month 12 encounter - \$25. Total compensation for encounters during the first 12 months post enrollment is \$150. Compensation will be made via a web-based payment system. Quarterly follow-up encounters will continue indefinitely starting at 15 months post enrollment. Subjects will be compensated \$10 via a web-based payment system for each of these encounters completed as previously described in this document. For encounters at 24 and 48 months post enrollment, subjects

will receive \$25 compensation as the survey instrument for these two follow-up visits is longer than the survey used at the other 15 plus months post-enrollment.

Control subjects (Study Population 2) will receive compensation for time and travel as follows:
Baseline visit - \$50.

If a potential subject/subject does not bring the required information such as an original, valid, government-issued photo identification and information about low back pain medications, the individual may receive a one-time \$10 payment to avoid undue hardship in covering time or travel costs. The potential subject/subject would still receive the appropriate amount of compensation scheduled for that encounter (\$50 for baseline visit or \$25 for each of the subsequent quarterly encounters) once the requested information is received. At the baseline visit, if the potential subject chooses to review the consent form at home prior to executing informed consent, he or she may also receive a \$10 payment. This would count as that subject's one-time \$10 payment if he or she enrolls in the study.

I. SUBJECT COSTS –

The only anticipated costs to subjects for this pain registry is the transportation cost for the initial visit to the UNTHSC campus. Subjects may also incur costs if they elect to complete additional encounters in person. These costs are minimal, and subjects will receive compensation sufficient to cover any travel expenses incurred.

J. LIST OF KEY PERSONNEL –

Principal Investigator:

John C. Licciardone, DO, MS, MBA, Family Medicine

Co-Investigators:

Subhash Aryal, PhD, Biostatistics

Robert Gatchel, PhD, Family Medicine

Jenny Lee, PhD, Family Medicine

David C. Mason, DO, MS, MBA, Family Medicine

Nicole Phillips, PhD, Microbiology, Immunology and Genetics

Other Key Personnel:

Cathleen Kearns, BA, Project Manager

Brooke Peters Beck, MS, Student Research Assistant (Formerly Kaleigh Brooke Peters)

Shweta Bhatnagar, Clinical Research Fellow

Maryam Burney, Clinical Research Fellow

Theodora Costin, Clinical Research Management Intern/Project Coordinator

Courtney Hall, Laboratory Technician

Samantha Johnson, BS, Project Coordinator

Jonathan Lopez, Clinical Research Fellow

Benjamin Romanowski, Clinical Research Fellow

Justin Salman, Clinical Research Fellow

Monika Schmitt, Clinical Research Fellow

Jie Sun, Laboratory Technician

Apollo Tran, Clinical Research Fellow

Annesha White, PharmD, MS, PhD, Pharmacogenetics Consultant

K. LITERATURE CITED – Please note that inline references are included in the text of the protocol synopsis.

Informed Consent:

V11

06-28-2018

**INFORMED CONSENT TO PARTICIPATE IN A RESEARCH PROJECT
for a Low Back Pain Registry**

TITLE: Pain Registry for Epidemiological, Clinical, and Interventional Studies
in North Texas (PRECISION TEXAS)

SUBSTUDY: The Osteopathic Difference in Treating Patients with Low Back Pain

PRINCIPAL INVESTIGATOR: John C. Licciardone, DO, MS, MBA

INSTITUTION: University of North Texas Health Science Center

NAME (Please Print): _____

IMPORTANT INFORMATION BEFORE YOU JOIN THIS STUDY

You are being invited to participate in a research registry project. This form explains your rights as a research participant. Please read it carefully and take your time to make your decision. If you have any questions, please feel free to ask the research coordinator. You may take an unsigned copy of this form home to think about or discuss with family or friends before making your decision. You will be given a copy of this form to keep.

SUMMARY

- There are no treatments or diagnoses provided in this research registry. We will ask you to use a computer or mobile device that we provide to answer questions that tell us about your experience with low back pain and how it affects your life, both physically and emotionally. We will also ask you for one saliva sample and a blood sample to use for genetic and biochemical analysis.
- Your participation in this research registry is voluntary and you may leave the registry at any time.
- It will not cost you anything to participate in the registry. We will pay you for your time to participate in the research registry. The first visit will be conducted in person at the University of North Texas Health Science Center campus in the cultural district in Fort Worth. You will be asked to complete quarterly encounters for an indefinite period of time. Those encounters may be completed by telephone, online or in-person. You will be compensated for each encounter you complete. Please note that we do not give compensation in cash.
- The first visit may take up to three hours. Each quarterly encounter through the first 12 months you are in the study will take about 30 minutes to one hour to complete. Encounters at 24 months and 48 months after you enroll in the study will also take approximately 30 minutes to one hour to

IRB APPROVED

AUG 07 2018

**NORTH TEXAS REGIONAL IRB
UNT HEALTH SCIENCE CENTER**

Subject Initials _____

Date _____

Page 1 of 7

complete. Quarterly follow-up encounters at 15, 18, 21, 27, 30, 33, 36, 39, 42 and 45 months after you enroll in the study will take 15-20 minutes to complete. Please note that you will need to provide a valid email address in order to complete the follow-up encounters online.

- You will be asked to bring the medicines (or list of medicines) you take for your low back pain to the initial visit. If you do not take medicine for low back pain, you will be asked to sign a form to certify this information. If you do not provide information about your low back pain medicines, we will not be able to enroll you in the registry.
- You will be asked to bring an original, valid, government-issued identification that includes your photo and birthdate to the first visit. If you do not bring the identification, you will not be enrolled in the study.
- You will be asked to complete an IRS W-9 form because compensation you receive for participating in the registry will be reported and taxed appropriately. You will need to know your social security number to complete the form. If you choose not to complete the W-9 form, you may still participate in the registry, but we will not be able to compensate you.
- Members of the research team will have access to the information you provide through surveys and to your biological data. All information will be stored by a unique number assigned to you instead of by your name, so members of the research team will not know whose information they are reviewing.
- Only a few members of the research team who conduct and oversee the encounters will have access to information that identifies you or links you to your data by name. Any forms or personal identifiable information is stored in a locked cabinet in a locked space.
- Research registries continue for an unspecified amount of time. Based on your participation in this registry, we may invite you to participate in future research studies on low back pain or other specific health conditions based on information you provide to us during this project. You may decide whether to participate in future studies or not at the time we invite you.

WHY ARE WE CONDUCTING THIS STUDY?

Millions of people in America suffer from low back pain. Some people have pain that lasts a few weeks or a few months, but many continue to have back pain most days of the month for several months or years.

We want to learn more about people's experience with low back pain and how it affects their daily life so we can use that information to help develop new ways to help people with low back pain feel better. We also plan to look at genes using the saliva samples we collect. Finally, we will ask you about medications you take and other treatments you receive for your low back pain.

By providing information about your experience with low back pain, you may help us learn more to help people with this problem in the future.

IRB APPROVED

AUG 07 2018

**NORTH TEXAS REGIONAL IRB
UNT HEALTH SCIENCE CENTER**

Subject Initials _____

Date _____

WHAT YOU WILL DO DURING THE STUDY

This is a research registry focused on low back pain. In a registry, members of the research team work with people who have a specific health condition, in this case, low back pain. The goal of the registry is to collect information that helps us better understand the natural history of low back pain and how it is treated.

In this registry, we will ask you to meet with a member of the research team at the University of North Texas Health Science Center, located in the cultural district in Fort Worth for the initial visit.

The longest visit will be the first one. During that visit, you will read and sign the consent document that confirms you agree to do the tasks we will be asking you to do. We will then ask you to answer a number of questions about your experience with low back pain and how it has affected your life. The questions are answered using a computer. You may stop and start as often as needed. The research coordinator will be available to assist you with any questions or problems in answering the questions.

Finally, we will ask you to give a sample of saliva for genetic analysis. Part of the saliva sample will also be stored to use for future tests. We will also have certified personnel draw three tubes of blood (approximately 2 tablespoons total). Part of the blood sample will also be stored for future tests. Both saliva and blood samples will be used to look at proteins, DNA and other substances that may be related to pain and other aspects of your health. Please note that saliva and blood are analyzed for research purposes only, and that potentially clinically-relevant results will not be shared with you or your healthcare provider.

Your name, any personal information that may identify you, or your contact information will not be stored with your answers to the questionnaire, saliva or blood sample.

The genetic (saliva) sample and the blood sample you give us will be stored indefinitely and may be analyzed multiple times for this project and for future research studies.

Only a few members of the research team who conduct and oversee the encounters will have access to information that identifies you or links you to that data by name.

You should plan up to three hours to complete this first study visit. We will compensate you \$50 for completing this visit. (Compensation will not be given in cash)

You are being asked to bring an original, valid, government-issued identification that includes a photo and birthdate, your social security number to complete the IRS W-9 form, and the medicines you take for low back pain or a list of those medicines to the first visit. If you do not take medicine for low back pain, you will be asked to sign a form to certify this information. If you do not bring your identification or your list of medicines, we will not be able to enroll you in the study. If you choose not to complete the W-9 form, you may still participate in the registry, but we will not be able to compensate you.

We value your participation in our research study, and it is important to us to have complete information from you, thus we may offer a one-time compensation of \$10 if you forget to bring either your identification, or your low back pain medicines or list to the initial visit.

IRB APPROVED

AUG 07 2018

NORTH TEXAS REGIONAL IRB
UNT HEALTH SCIENCE CENTER

Subject Initials _____

Date _____

You will be asked to complete follow-up encounters approximately every three months to answer questions. During the first year after you enroll in the study, each of these encounters will take approximately 30 minutes to one hour. We will remind you of your upcoming visit using your preferred method of communication. These encounters may be completed by telephone, online or in-person. Please note that you will need to provide a valid email address in order to complete follow-up encounters online. You may also complete these encounters by telephone or in-person. You will receive compensation of \$25 for each quarterly encounter that you complete through 12 months after you enroll in the study. (Compensation will not be given in cash)

Encounters at 24 months and 48 months after you enroll in the study will also take approximately 30 minutes to one hour to complete. Quarterly follow-up encounters at 15, 18, 21, 27, 30, 33, 36, 39, 42 and 45 months after you enroll in the study will take 15-20 minutes to complete. You will receive compensation of \$10 for each quarterly follow-up encounter at 15, 18, 21, 27, 30, 33, 36, 39, 42 and 45 months post-enrollment that you complete. For the 24-month and 48-month encounters only, you will receive \$25. These encounters will be completed by phone, online, or in-person. (Compensation will not be given in cash)

During these quarterly encounters, you may be asked questions about specific treatments you may have received for low back pain, your response to those treatments, how you might perceive pain in different circumstances, and medications you take for other medical conditions.

You may be contacted between study encounters to clarify study-related data.

RISKS AND DISCOMFORTS

Questionnaires

The risks associated with this study are a minor increase over minimal risk.

You may feel uncomfortable answering some of the questions in the survey. On rare occasions, answers you provide may accidentally be revealed to someone other than members of the research team. However, members of the research team will take all precautions necessary to protect your confidentiality as a research study participant. None of your personal identifying information, such as your name or address, will be recorded in the questionnaire response database. Results from this study will not report any of your personal identifying information.

Genetics

On rare occasions, someone outside of the research team may accidentally see your genetic data. Again, the research team will minimize this risk by ensuring that your personal information such as your name and address are not stored with DNA results. Genetic information is stored on a separate computer from any personal identifying information in order to create another layer of security. Any genetic results from this study will not include any of your personal identifying information.

On rare occasions, insurers or government agencies have requested information about a specific person's genetic information from research studies. However, we are applying for a Certificate of Confidentiality to offer you and other study participants an added layer of protection to prevent any personal identifying information from being released against your wishes. Please carefully read the section about

IRB APPROVED

AUG 07 2018

NORTH TEXAS REGIONAL IRB
UNT HEALTH SCIENCE CENTER

Subject Initials _____

Date _____

Confidentiality to understand more about how this Certificate helps protect information you provide to us during this study.

Blood Draw

There is very little risk associated with drawing blood. Your arm may feel sore and may bruise. Any soreness or bruising usually goes away in a few days. Occasionally, you may bleed from the site where blood was drawn for a few minutes, or you may feel lightheaded. If you have any problems after the blood draw, please tell laboratory personnel or the research coordinator.

COMPENSATION FOR INJURY

We, at the University of North Texas Health Science Center at Fort Worth, have not set aside any funds for financial compensation or costs of medical treatment if you get injured as a result of your participation in this research.

If required, medical care will be made available to you in the case of such injury, but you (or your private insurer, Medicare, Medicaid, or other governmental health care program) will be responsible for the expense of any medical care if needed.

You should know that by signing this form, you are neither waiving any of your legal rights against or releasing the principal investigator, the University of North Texas Health Science Center at Fort Worth, or any of their respective agents from liability for negligence with respect to the conduct of the study. If you are injured and feel that your injury justifies a legal remedy, you have the right to do so.

CONTACTS

If a study-related problem occurs, or if you have any questions about your participation in the study, you may contact Cathleen Kearns, research assistant director, at 817-735-0515. You may also contact the study investigator, Dr. John Licciardone, at 817-735-0515. You may send questions about your participation in the study to Ms. Kearns or Dr. Licciardone by email to prcstudyoperations@unthsc.edu. Please note that other authorized members of the research team have access to this email box and may see your message.

If you have questions about your rights as a participant in this registry, you may contact the North Texas Regional Institutional Review Board Chair, at the University of North Texas Health Science Center at Fort Worth at 817-735-0409.

BENEFITS

You may not receive any direct benefit from participating in this registry. The information gained from this research may help develop new ways to treat low back pain in the future or to help individualize current treatments for low back pain.

CONFIDENTIALITY

Your privacy and confidentiality are very important to members of the research team. In addition to storing personal identifying information separate from responses to questions and from your genetic information, we store all information in password-protected files.

IRB APPROVED

AUG 07 2018

**NORTH TEXAS REGIONAL IRB
UNT HEALTH SCIENCE CENTER**

Subject Initials _____

Date _____

Because we are collecting genetic information in this registry, we are planning to obtain a Certificate of Confidentiality, issued by the National Institutes of Health. This Certificate will allow researchers to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceeding (for example, if there is a court subpoena). The researchers will use the Certificate to resist any demands for information that would identify you.

A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person has your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities if you provide information that suggests you are abusing a child in your care or if you provide information that suggests you are a clear danger to yourself or others.

AUTHORIZATION TO USE HEALTH INFORMATION

Members of the research team will be able to see health information that you provide during this study such as treatments that you have received for your low back pain and medications that you report taking for low back pain. We will not ask for any personal medical records in addition to the questions we ask you to answer, the saliva sample, and the blood sample that we collect.

COSTS AND PAYMENTS OF THE STUDY

There are no costs to participate in this research registry except travel costs to attend in-person visits at the UNT Health Science Center. If you choose to receive appointment reminders by text message, standard text messaging rates will apply. As compensation for your time, you will receive \$50 after completing the first visit, and \$25 for each of the remaining four encounters in the first 12 months after enrolling in the registry. Compensation is provided at the end of each in-person visit. For visits completed by phone or online, payment will be made within two business days of completing the encounter. If you complete all five encounters in the first 12 months of the study, you will receive a total of \$150. In addition, we will follow-up with you quarterly starting at 15 months after you enroll in the study. These quarterly encounters are conducted by phone, online or in-person. You will receive \$10 as compensation for completing encounters at 15, 18, 21, 27, 30, 33, 36, 39, 42 and 45 months post-enrollment. Encounters at 24 months post-enrollment and 48 months post-enrollment will be compensated at the rate of \$25 because the surveys for these two visits are longer than the quarterly surveys listed above. (Compensation will not be given in cash)

The research team will discuss the payment process with you and will provide specific instructions.

As a research participant, your compensation is subject to federal tax at standard rates. Compensation for this study falls under the federal threshold of \$600 (total) per year, so you would not be taxed on the compensation received for this study unless you receive other miscellaneous income from the UNT Health Science Center that, combined with compensation from this study, exceeds \$600. This applies only to compensation received from this point forward.

IRB APPROVED

AUG 07 2018

**NORTH TEXAS REGIONAL IRB
UNT HEALTH SCIENCE CENTER**

Subject Initials _____

Date _____

LEAVING THE STUDY

Your participation in this study is completely voluntary. You may withdraw your permission to use your information, saliva and blood sample at any time.

You also have the right to stop participating in the registry or to ask us not to contact you at any time. In this case, we would continue to use the information you have provided up to that point as well as your saliva and blood samples unless you send us a written request asking us to discard these items.

Any such request must be made in writing to Dr. John Licciardone, University of North Texas Health Science Center, 3500 Camp Bowie Boulevard, Fort Worth, TX 76107.

If you are a patient at the UNT Health Science Center or any of its affiliated clinics, withdrawing from the study will not affect your medical care in any way.

If you are a student or employee of the UNT Health Science Center, your participation or non-participation will in no way affect your academic standing or employment status.

The principal investigator reserves the right to ask you to leave the study at any time if he believes it is in your or the study's best interest.

CONSENT

You will receive a copy of this signed agreement.

I voluntarily agree to participate in this research registry. I have had the chance to ask the research team any questions I have regarding this registry.

I have been told that to participate in this registry, I need to give a saliva sample for genetic analysis, and a blood sample for protein, DNA and biochemical analysis. I agree to allow my saliva and blood samples to be used for this project and for future projects. I understand that my blood and saliva are being analyzed for research purposes only, and that potentially clinically-relevant results will not be given to me or my healthcare provider.

I have been told that I will be contacted at regular intervals for an indefinite period of time to update my contact information and to provide information about my low back pain.

I have been told that I may be contacted to clarify information provided during study encounters, and that I may also be invited to participate in future studies based on specific information I provide during my participation in this research registry.

Signature of Study Participant

Date

Signature of Person Obtaining Informed Consent

Date

IRB APPROVED

AUG 07 2018

**NORTH TEXAS REGIONAL IRB
UNT HEALTH SCIENCE CENTER**

Subject Initials _____

Date _____

Page 7 of 7

HIPAA:

Study Title: Pain Registry for Epidemiological, Clinical, and Interventional Studies in North Texas (PRECISION Texas) **Substudy:** The Osteopathic Difference in Treating Patients with Low Back Pain

IRB APPROVED

Principal Investigator Name: John C. Licciardone, DO, MS, MBA

AUG 07 2018

**NORTH TEXAS REGIONAL IRB
UNT HEALTH SCIENCE CENTER**

A. What is the purpose of this form?

The purpose of this form is to give your permission to the research team at [the University of North Texas Health Science Center ("UNTHSC")] to obtain, use or share your protected health information (PHI). This protected health information will be used to do the research named above. UNTHSC understands that information about you and your health is personal and we are committed to protecting the privacy of that information in accordance with state and federal privacy laws. Because of this commitment, we must obtain your written authorization before we may collect, use or share your protected health information for the research study listed above. This form provides authorization and helps us make sure you are properly informed of how this information will be used or disclosed. You do not have to sign this permission form. If you do not sign, UNTHSC will not obtain, use or share your protected health information for research. Please note though that you will not be able to participate in the research study. Your decision to not sign this permission will not affect any treatment, health care, enrollment in health plans or eligibility for benefits.

B. What is considered Protected Health Information (PHI)?

In this form, "protected health information" (PHI) refers to any health information that identifies you, such as:

- Your past, present, or future physical or mental health or condition (e.g., lab results)
- Health care provided to you (e.g., x-rays)
- The past, present, or future payment for providing your health care (e.g., billing/payment information).
- Genetic information

C. What Protected Health Information will be obtained, used or shared?

If you sign this form, you give UNTHSC permission to obtain, use or share the following health information as part of this research study:

Examples of the type of information that may be used or shared during this study include:

1. Information from your research record.

will still receive the same clinical care, or any services you were already entitled to receive. However, if you do not sign the document, you will not be able to participate in this research study.

H. Does my permission expire?

This permission to release your Protected Health Information expires when the research ends and all required study monitoring is over.

I. Can I cancel my permission?

You can cancel your permission at any time.

You can do this by writing to the researcher. Please send your written request to:

*Dr. John C. Licciardone
Department of Family Medicine, University of North Texas Health Science Center
3500 Camp Bowie Boulevard
Fort Worth, TX 76107*

You have the right to take back your permission at any time, except to the extent that the research team has already taken action in reliance on your permission. If you cancel your permission, you may no longer be in the research study.

If you cancel, no more health information about you will be collected. However, information that has already been collected and disclosed about you may continue to be used as necessary to maintain the integrity of the study (i.e. complete the research). Also, if the law requires it, the sponsor and government agencies may continue to look at your protected health information to review the quality or safety of the study.

J. QUESTIONS CONCERNING YOUR PRIVACY RIGHTS?

Please call Cathleen Kearns at 817-735-0515 with any questions.

K. Authorization

If you agree to the use and release of your Protected Health Information, please sign below.

IRB APPROVED

AUG 07 2018

**NORTH TEXAS REGIONAL IRB
UNT HEALTH SCIENCE CENTER**

Required Signature for HIPAA Authorization:

Subject name (print)

Subject signature:

Date

Witness

If this form is being read to the subject because s/he cannot read the form, a witness must be present and is required to print his/her name and sign here:

Witness' Name (print)

Witness' Signature

Date

You will receive a copy of this signed form. Please keep it with your personal records.

IRB APPROVED

AUG 07 2018

**NORTH TEXAS REGIONAL IRB
UNT HEALTH SCIENCE CENTER**

Qualtrics Screening Questionnaire

SQ FORM INTRODUCTION

Q1. Thank you for your interest in our research registry for people with low back pain. There are **NO DIAGNOSES OR TREATMENTS** provided in this research registry. We collect information about low back pain, including one-time samples of saliva and blood that will be analyzed for DNA, proteins, and other biological substances to learn about low back pain and how it affects people's lives. If you qualify, you must attend an initial visit at the University of North Texas Health Science Center in the Cultural District of Fort Worth. Regular quarterly follow-ups will be conducted in person, by telephone, or online for an indefinite period of time. We will contact you by mail, telephone, or e-mail to arrange these follow-ups. If you qualify, you will be compensated for participating in the registry. You must complete the next section of this questionnaire about your health to determine if you are eligible to participate in the registry. Your responses will be retained by our research team, but will not be shared with others. You may exit the questionnaire at any time if you do not wish to provide the required information. If you are eligible, you must provide the requested contact information for our research team to follow-up with you to complete the enrollment process.

Your Rights as a Prospective Research Participant

This is a voluntary research study to help us learn more about low back pain. If enrolled, you may withdraw from the study at any time. There is no direct benefit to you for participating in this research registry, but the information gained from this research may help develop new ways to treat low back pain in the future or help individualize current treatments for low back pain.

Your information will be kept as confidential as possible. All information collected is kept in secure and/or password protected areas. There is a risk of loss of privacy related to the information collected, but we have processes to minimize this risk.

If you have any questions about your participation in the study, you may contact Cathleen Kearns, research assistant director, at 817-735-0515, or by email at orestudyoperations@unthsc.edu. If you have questions about your rights as a prospective participant in this registry, you may contact the North Texas Regional Institutional Review Board at the University of North Texas Health Science Center at Fort Worth at 817-735-0409.

SCREENING QUESTIONS

Q2. How did you find out about our pain research registry?

Q3. How long have you had low back pain?

- | | |
|---|---|
| ☐ I have never had low back pain | ☐ 6 months to 1 year |
| ☐ Less than 1 month | ☐ 1-5 years |
| ☐ 2-3 months | ☐ More than 5 years |
| ☐ 3-6 months | |

Q4. How many days did you have low back pain during the past 2 months?

- ☐ Every day or nearly every day in the past 2 months
- ☐ At least half of the days in the past 2 months
- ☐ Less than half of the days in the past 2 months

Q5. Which of the following best describes that doctor who usually provides medical care for your low back pain?

- ☐ Medical doctor (MD)
- ☐ Osteopathic doctor (DO)
- ☐ I have a doctor who usually provides medical care for my low back pain, but do not know if the doctor is an MD or DO
- ☐ I do not have a doctor who usually provides medical care for my low back pain

IRB APPROVED

AUG 07 2018

**NORTH TEXAS REGIONAL IRB
UNT HEALTH SCIENCE CENTER**

Q6. How long have you had the doctor who usually provides medical care for your low back pain?

___ Less than 1 month ___ 6 months to 1 year

___ 1-3 months ___ 1-5 years

___ 3-6 months ___ More than 5 years

___ I do not have a doctor who usually provides medical care for my low back pain

Q7. Are you in the range of 21 to 79 years of age? ___ Yes ___ No

Q8. Are you pregnant? ___ Yes ___ No

IRB APPROVED

AUG 07 2018

**NORTH TEXAS REGIONAL IRB
UNT HEALTH SCIENCE CENTER**

INELIGIBILITY STATEMENT

Q9. You are not eligible to participate in the pain research registry at this time. If you provide your contact information below, we may contact you at a later date to determine if you qualify for our registry or other research studies. You need not provide the contact information below if you do not wish to be contacted in the future for study eligibility.

Q10. Provide your first and last name.

Q11. Provide a telephone number that we may use to contact you during normal business hours.

Q12. Provide an e-mail address.

ELIGIBILITY STATEMENT

Q13. You appear to be eligible to participate in the pain research registry based on the responses provided. Provide the information below so that we may contact you to discuss enrollment in the registry. You may contact us at 817-735-5410 if you have any questions.

Q14. Provide your first and last name.

Q15. Provide a telephone number that we may use to contact you during business hours and your zip code.

Q16. Provide an e-mail address.

APPROVED • AUGUST xx, 2018 • NORTH TEXAS REGIONAL IRB

IRB APPROVED

AUG 07 2018

SA FORM INTRODUCTION

**NORTH TEXAS REGIONAL IRB
UNT HEALTH SCIENCE CENTER**

Q1.

Thank you for participating in our survey. Your responses are very important to us. The survey questions ask you about various aspects of your low back pain, including treatments that you have received. You must complete an entire section before proceeding to the next section. You may take breaks if needed to complete the survey. Although some questions may appear similar or repetitious, it is important that you answer each of them as accurately as possible as you proceed through the survey.

ENCOUNTER INFORMATION

Q2. I.D. Number:

Q3. Today's date (MM/DD/YYYY):

INFORMATION ABOUT YOUR LOW BACK PAIN

Q4. How long has low back pain been an ongoing problem for you?

- ☐ Less than 1 month
- ☐ 1 month
- ☐ 2-3 months
- ☐ 3-6 months
- ☐ 6 months-1 year
- ☐ 1-5 years
- ☐ More than 5 years

Q5. How often has low back pain been an ongoing problem for you over the past 2 months?

- ☐ Every day or nearly every day in the past 2 months
- ☐ At least half of the days in the past 2 months
- ☐ Less than half of the days in the past 2 months

Q6. How often has low-back pain been an ongoing problem for you over the past 6 months?

- ☐ Every day or nearly every day in the past 6 months
- ☐ At least half of the days in the past 6 months
- ☐ Less than half the days in the past 6 months

Q7.

In the past 7 days, how would you rate your low-back pain on average?

RATE YOUR PAIN AS A NUMBER FROM 0 TO 10

(0 indicates no pain. Higher numbers represent more pain. 10 indicates the worst possible pain.)

No pain											Worst pain
0	1	2	3	4	5	6	7	8	9	10	
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	

Q8. Has back pain spread down your leg(s) during the past 2 weeks?

- ☐ Yes
- ☐ No
- ☐ Not sure

Q9. During the past 4 weeks, how much have you been bothered by ...

	Not at all	A little bit	A lot
Stomach pain?	☐	☐	☐
Pain in your arms, legs, or joints other than your spine or back?	☐	☐	☐
Headaches?	☐	☐	☐
Widespread pain or pain in most of your body?	☐	☐	☐

Q10. Have you ever had a low back operation?

- ☐ Yes, one operation
- ☐ Yes, more than one operation
- ☐ No

Q11.

Have you ever been unemployed or unable to do your usual work for 1 month or longer due to low back pain?

- ☐ Yes
- ☐ No

Q12. Have you ever received disability or workers' compensation benefits because you were unable to work due to low back pain?

- ☐ Yes
- ☐ No
- ☐ This question DOES NOT APPLY TO ME because I have never been employed or worked in a setting that provided eligibility to receive disability or workers' compensation benefits

Q13. Have you ever been involved in a lawsuit or legal claim related to your low back pain?

- ☐ Yes
- ☐ No

IRB APPROVED

AUG 07 2018

**NORTH TEXAS REGIONAL IRB
UNT HEALTH SCIENCE CENTER**

Q14. What is your age?

Q15. What is your gender?

- ☐ Male
- ☐ Female

Q16. What is your ethnicity? (SELECT THE ONE WITH WHICH YOU MOST CLOSELY IDENTIFY)

- ☐ Hispanic or Latino
- ☐ Not Hispanic or Latino

Q17. What is your race? (SELECT THE ONE WITH WHICH YOU MOST CLOSELY IDENTIFY)

- ☐ American Indian or Alaskan Native
- ☐ Asian
- ☐ Black or African American
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ White

Q18. What is your employment status?

- ☐ Working now
- ☐ Looking for work, unemployed
- ☐ Sick leave or maternity leave
- ☐ Disabled due to back pain, permanently or temporarily
- ☐ Disabled for reasons other than back pain
- ☐ Student
- ☐ Temporarily laid off
- ☐ Retired
- ☐ Keeping house
- ☐ Other

Q19. What is your education level? (SELECT THE HIGHEST ONE ATTAINED)

- ☐ No high school diploma
- ☐ High school graduate or GED
- ☐ Some college, no degree
- ☐ Occupational/technical/vocational program
- ☐ Associate's degree
- ☐ Bachelor's degree
- ☐

IRB APPROVED

AUG 07 2018

**NORTH TEXAS REGIONAL IRB
UNT HEALTH SCIENCE CENTER**

Master's degree

- ☐ Professional school degree (e.g., physician, dentist, attorney)
- ☐ Doctoral degree (e.g., Ph.D)

IRB APPROVED

AUG 07 2018

NORTH TEXAS REGIONAL IRB
UNT HEALTH SCIENCE CENTER

Q20. How would you describe your cigarette smoking?

- ☐ Never smoked
- ☐ Current smoker
- ☐ Used to smoke, but have now quit

Q21. What is your height in inches?

Q22. What is your weight in pounds?

HOW LOW BACK PAIN AFFECTS YOUR ACTIVITIES (RMDQ-24)

Q23. The questions in this section contain sentences that people have used to describe themselves when they have back pain. When you read them, you may find that some stand out because they describe you today. SELECT "YES" OR "NO" BASED ONLY ON HOW YOU FEEL TODAY.

	Yes	No
I stay home most of the time because of the pain in my back.	☐	☐
I change position frequently to try and make my back comfortable.	☐	☐
I walk more slowly than usual because of the pain in my back.	☐	☐
Because of the pain in my back, I am not doing any of the jobs that I usually do around the house.	☐	☐
Because of the pain in my back, I use a handrail to get up stairs.	☐	☐
Because of the pain in my back, I lie down to rest more often.	☐	☐
Because of the pain in my back, I have to hold on to something to get out of a reclining chair.	☐	☐
Because of the pain in my back, I ask other people to do things for me.	☐	☐
I get dressed more slowly than usual because of the pain in my back.	☐	☐

	Yes	No
I only stand up for short periods of time because of the pain in my back.	☐	☐
Because of the pain in my back, I try not to bend or kneel down.	☐	☐
I find it difficult to get out of a chair because of the pain in my back.	☐	☐
My back hurts most of the time.	☐	☐
I find it difficult to turn over in bed because of the pain in my back.	☐	☐
My appetite is not very good because of the pain in my back.	☐	☐
I have trouble putting on my socks (or stockings) because of the pain in my back.	☐	☐
I only walk short distances because of the pain in my back.	☐	☐
I sleep less because of the pain in my back.	☐	☐
Because of the pain in my back, I get dressed with help from someone else.	☐	☐
I sit down for most of the day because of the pain in my back.	☐	☐
I avoid heavy jobs around the house because of the pain in my back.	☐	☐
Because of the pain in my back, I am more irritable and bad tempered with people.	☐	☐
Because of the pain in my back, I go up stairs more slowly than usual.	☐	☐
I stay in bed most of the time because of the pain in my back.	☐	☐

HOW LOW BACK PAIN AFFECTS YOUR LIFE (PROMIS-29)

Q24. Please answer the following 4 questions.

	Without any difficulty	With a little difficulty	With some difficulty	With much difficulty	Unable to do
Are you able to do chores such as vacuuming or yard work?	☐	☐	☐	☐	☐
Are you able to go up and down stairs at a normal pace?	☐	☐	☐	☐	☐
Are you able to go for a walk of at least 15 minutes?	☐	☐	☐	☐	☐
Are you able to run errands and shop?	☐	☐	☐	☐	☐

IRB APPROVED

AUG 07 2018

**NORTH TEXAS REGIONAL IRB
UNT HEALTH SCIENCE CENTER**

IRB APPROVED

AUG 07 2018

NORTH TEXAS REGIONAL IRB
UNT HEALTH SCIENCE CENTER

Q25.

Please respond to the following 4 statements.

In the past 7 days...

	Never	Rarely	Sometimes	Often	Always
I felt fearful.	☐	☐	☐	☐	☐
I found it hard to focus on anything other than my anxiety.	☐	☐	☐	☐	☐
My worries overwhelmed me.	☐	☐	☐	☐	☐
I felt uneasy.	☐	☐	☐	☐	☐

Q26.

Please respond to the following 4 statements.

In the past 7 days ...

	Never	Rarely	Sometimes	Often	Always
I felt worthless.	☐	☐	☐	☐	☐
I felt helpless.	☐	☐	☐	☐	☐
I felt depressed.	☐	☐	☐	☐	☐
I felt hopeless.	☐	☐	☐	☐	☐

Q27.

Please respond to the following 4 statements or questions.

During the past 7 days...

	Not at all	A little bit	Somewhat	Quite a bit	Very much
I felt fatigued.	☐	☐	☐	☐	☐
I have had trouble starting things because I am tired.	☐	☐	☐	☐	☐
How run-down did you feel on average?	☐	☐	☐	☐	☐
How fatigued were you on average?	☐	☐	☐	☐	☐

Q28. In the past 7 days...

	Very poor	Poor	Fair	Good	Very good
My sleep quality was ...	☐	☐	☐	☐	☐

Q29.

Please respond to the following 3 statements.

In the past 7 days...

	Not at all	A little bit	Somewhat	Quite a bit	Very much
My sleep was refreshing.	☐	☐	☐	☐	☐
I had a problem with my sleep.	☐	☐	☐	☐	☐
I had difficulty falling asleep.	☐	☐	☐	☐	☐

Q30. Please respond to the following 4 statements.

	Never	Rarely	Sometimes	Usually	Always
I have trouble doing all of my regular leisure activities with others.	☐	☐	☐	☐	☐
I have trouble doing all of the family activities that I want to do.	☐	☐	☐	☐	☐
I have trouble doing all of my usual work (include work at home).	☐	☐	☐	☐	☐
I have trouble doing all of the activities with friends that I want to do.	☐	☐	☐	☐	☐

Q31.

Please answer the following 4 questions.

In the past 7 days...

	Not at all	A little bit	Somewhat	Quite a bit	Very much
How much did pain interfere with your day-to-day activities?	☐	☐	☐	☐	☐
How much did pain interfere with work around the home?	☐	☐	☐	☐	☐
How much did pain interfere with your ability to participate in social activities?	☐	☐	☐	☐	☐
How much did pain interfere with your household chores?	☐	☐	☐	☐	☐

HOW YOU THINK AND FEEL ABOUT PAIN (PCS-13)

Q32. Everyone experiences painful situations at some point in their lives. Such experiences may include headaches, tooth pain, joint, or muscle pain. People are often exposed to situations that may cause pain, such as illness, injury, dental procedures, or surgery.

We are interested in the types of thoughts and feelings that you have when you are in pain. Answer the questions in this section about different thoughts and feelings that may be associated with pain. Please indicate the degree to which you have these thoughts and feelings when you are experiencing pain.

	Not at all	To a slight degree	To a moderate degree	To a great degree	All the time
I worry all the time about whether the pain will end.	☐	☐	☐	☐	☐
I feel I can't go on.	☐	☐	☐	☐	☐
It's terrible and I think it's never going to get any better.	☐	☐	☐	☐	☐
It's awful and I feel that it overwhelms me.	☐	☐	☐	☐	☐
I feel I can't stand it anymore.	☐	☐	☐	☐	☐
I become afraid that the pain will get worse.	☐	☐	☐	☐	☐
I keep thinking of other painful events.	☐	☐	☐	☐	☐
I anxiously want the pain to go away.	☐	☐	☐	☐	☐

IRB APPROVED

AUG 07 2018

NORTH TEXAS REGIONAL IRB

	Not at all	To a slight degree	To a moderate degree	To a great degree	All the time
I can't seem to keep it out of my mind.	☐	☐	☐	☐	☐
I keep thinking about how much it hurts.	☐	☐	☐	☐	☐
I keep thinking about how badly I want the pain to stop.	☐	☐	☐	☐	☐
There's nothing I can do to reduce the intensity of the pain.	☐	☐	☐	☐	☐
I wonder whether something serious may happen.	☐	☐	☐	☐	☐

IRB APPROVED

CONFIDENCE IN LIVING AND COPING WITH PAIN (PSEQ-10)

AUG 07 2018

Q33.

Answer the questions in this section about your confidence in performing various activities.

NORTH TEXAS REGIONAL IRB
UNT HEALTH SCIENCE CENTER

RATE YOUR CONFIDENCE AS A NUMBER FROM 0 TO 6.

(0 indicates that you are not confident at all. Higher numbers represent more confidence. 6 indicates that you are completely confident.)

	Not at all confident 0	1	2	3	4	5	Completely confident 6
I can enjoy things, despite the pain.	☐	☐	☐	☐	☐	☐	☐
I can do most of the household chores (e.g., tidying-up, washing dishes, etc.), despite the pain.	☐	☐	☐	☐	☐	☐	☐
I can socialize with my friends or family members as often as I used to, despite the pain.	☐	☐	☐	☐	☐	☐	☐
I can cope with my pain in most situations.	☐	☐	☐	☐	☐	☐	☐
I can do some form of work, despite the pain (work includes housework, paid and unpaid work).	☐	☐	☐	☐	☐	☐	☐
I can still do many of the things I enjoy doing, such as hobbies or leisure activity, despite the pain.	☐	☐	☐	☐	☐	☐	☐
I can cope with my pain without medication.	☐	☐	☐	☐	☐	☐	☐
I can still accomplish most of my goals in life, despite the pain.	☐	☐	☐	☐	☐	☐	☐
I can live a normal lifestyle, despite the pain.	☐	☐	☐	☐	☐	☐	☐
I can gradually become more active, despite the pain.	☐	☐	☐	☐	☐	☐	☐

THE DOCTOR WHO TREATS YOUR LOW BACK PAIN

Q34.

Answer the questions in this section about the DOCTOR WHO USUALLY PROVIDES MEDICAL CARE FOR YOUR LOW BACK PAIN. IN MOST CASES THIS WILL BE YOUR PRIMARY CARE PHYSICIAN (PCP); HOWEVER, IF ANOTHER DOCTOR USUALLY PROVIDES MEDICAL CARE FOR YOUR LOW BACK PAIN THEN ANSWER

THE QUESTIONS BASED ON YOUR EXPERIENCE WITH THAT DOCTOR. Do not consider other doctors when answering these questions.

Q35. Which of the following best describes the doctor who usually provides medical care for your low back pain?

- ☐ MD (medical doctor)
- ☐ DO (osteopathic doctor)

Q36. How long have you had the doctor who usually provides medical care for your low back pain?

- ☐ Less than 1 month
- ☐ 1-3 months
- ☐ 3-6 months
- ☐ 6 months to 1 year
- ☐ 1-5 years
- ☐ More than 5 years

TREATMENTS FOR LOW BACK PAIN

Q37. Have you EVER USED opioid (narcotic) painkillers for your low back pain? These may include such prescription drugs as Codeine, Dilaudid, Duragesic, Fentanyl, Hydrocodone, Hydromorphone, Lortab, Methadone, Morphine, MS Contin, Norco, Oxycodone, OxyContin, Oxymorphone, Percocet, Tramadol, Tylenol #3 or #4, Tylox, Ultram, Vicodin, and others.

- ☐ Yes
- ☐ No

Q38. Are you CURRENTLY USING opioid (narcotic) painkillers for pain? These may include such prescription drugs as Codeine, Dilaudid, Duragesic, Fentanyl, Hydrocodone, Hydromorphone, Lortab, Methadone, Morphine, MS Contin, Norco, Oxycodone, OxyContin, Oxymorphone, Percocet, Tramadol, Tylenol #3 or #4, Tylox, Ultram, Vicodin, and others.

- ☐ Yes
- ☐ No

Q39. Have you EVER USED nonsteroidal anti-inflammatory drugs (NSAIDs) for your low back pain? These may include such prescription or over-the-counter drugs as Advil, Aleve, Anaprox, Aspirin, Celebrex, Celecoxib, Ibuprofen, Motrin, Naprosyn, Naproxen, and others.

- ☐ Yes
- ☐ No

Q40. Are you CURRENTLY USING nonsteroidal anti-inflammatory drugs (NSAIDs) for pain? These may include such prescription or over-the-counter drugs as Advil, Aleve, Anaprox, Aspirin, Celebrex, Celecoxib, Ibuprofen, Motrin, Naprosyn, Naproxen, and others.

- ☐ Yes
- ☐ No

IRB APPROVED

AUG 07 2018

**NORTH TEXAS REGIONAL IRB
UNT HEALTH SCIENCE CENTER**

Q41. Have you EVER received or participated in any of the following treatments for your low back pain? (SELECT ALL THAT APPLY)

- ☐ Exercise therapy at a facility outside your home
- ☐ Yoga
- ☐ Massage therapy
- ☐ Spinal manipulation
- ☐ Cognitive-behavioral therapy
- ☐ Acupuncture
- ☐ I have NOT EVER received or participated in any of these treatments for low back pain

MEDICAL CONDITIONS

Q42. Have you EVER been diagnosed with any of the following conditions? (SELECT ALL THAT APPLY)

- ☐ Herniated disc in your lower back
- ☐ Sciatica
- ☐ Osteoporosis
- ☐ Osteoarthritis
- ☐ Rheumatoid arthritis
- ☐ Heart disease
- ☐ Hypertension
- ☐ Diabetes
- ☐ Asthma
- ☐ Chronic bronchitis
- ☐ Depression
- ☐ I have NOT EVER been diagnosed with any of the conditions listed above

IRB APPROVED

AUG 07 2018

**NORTH TEXAS REGIONAL IRB
UNT HEALTH SCIENCE CENTER**

INTERACTIONS WITH YOUR DOCTOR (CBQ-23)

Q43.

Answer the questions in this section about the DOCTOR WHO USUALLY PROVIDES MEDICAL CARE FOR YOUR LOW BACK PAIN. Do not consider other doctors when answering these questions.

Q44. The doctor has ...

	Strongly agree	Agree	Somewhat agree	Somewhat disagree	Disagree	Strongly disagree
Weighed the advantages and disadvantages of different treatment options with you.	☐	☐	☐	☐	☐	☐
Set treatment and therapy measures in a joint discussion with you.	☐	☐	☐	☐	☐	☐
Discussed the treatment plan with you.	☐	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐	☐

	Strongly agree	Agree	Somewhat agree	Somewhat disagree	Disagree	Strongly disagree
Explained the procedure of your treatment to you thoroughly.	☐	☐	☐	☐	☐	☐
Asked you what helped you in your treatment and what did not.	☐	☐	☐	☐	☐	☐
Discussed the next stage of treatment with you.	☐	☐	☐	☐	☐	☐
Asked you everything about your illness.	☐	☐	☐	☐	☐	☐
Explained the procedure for your treatment.	☐	☐	☐	☐	☐	☐
Listened carefully when you wanted to say something.	☐	☐	☐	☐	☐	☐
Informed you at the end of treatment about the further treatment of your illness.	☐	☐	☐	☐	☐	☐
Informed you openly and directly of things concerning your illness that could be stressful (e.g., side effects of a treatment).	☐	☐	☐	☐	☐	☐
Asked about all your symptoms.	☐	☐	☐	☐	☐	☐
Always told you everything about your illness, even if it was unpleasant.	☐	☐	☐	☐	☐	☐
Asked you what you want to know about your treatment.	☐	☐	☐	☐	☐	☐
Asked whether you experienced pain during therapy/treatment.	☐	☐	☐	☐	☐	☐
Explained to you exactly what your diagnosis means.	☐	☐	☐	☐	☐	☐
Always been optimistic and upbeat during talks with you.	☐	☐	☐	☐	☐	☐
Always given you encouragement during talks.	☐	☐	☐	☐	☐	☐
Always been very even-tempered during talks.	☐	☐	☐	☐	☐	☐
Sometimes laughed when talking with you.	☐	☐	☐	☐	☐	☐
Sometimes spoken with you on a personal level.	☐	☐	☐	☐	☐	☐
Sometimes talked with you about things that have nothing to do with your illness.	☐	☐	☐	☐	☐	☐
Occasionally talked to you about private matters.	☐	☐	☐	☐	☐	☐

INTERACTIONS WITH YOUR DOCTOR (CARE-10)

Q45.

Answer the questions in this section about the DOCTOR WHO USUALLY PROVIDES MEDICAL CARE FOR YOUR LOW BACK PAIN. Do not consider other doctors when answering these questions.

IRB APPROVED

AUG 07 2018

**NORTH TEXAS REGIONAL IRB
UNT HEALTH SCIENCE CENTER**

Q46. How was the doctor at ...

	Excellent	Very good	Good	Fair	Poor
Making you feel at ease (being friendly and warm towards you, treating you with respect; not cold or abrupt)?	☐	☐	☐	☐	☐
Letting you tell your "story" (giving you time to fully describe your illness in your own words; not interrupting or diverting you)?	☐	☐	☐	☐	☐
Really listening (paying close attention to what you were saying; not looking at the notes or computer as you were talking)?	☐	☐	☐	☐	☐
Being interested in you as a whole person (asking/knowing relevant details about your life, your situation; not treating you as "just a number")?	☐	☐	☐	☐	☐
Fully understanding your concerns (communicating that he/she had accurately understood your concerns; not overlooking or dismissing anything)?	☐	☐	☐	☐	☐
Showing care and compassion (seeming genuinely concerned, connecting with you on a human level; not being indifferent or "detached")?	☐	☐	☐	☐	☐
Being positive (having a positive approach and a positive attitude; being honest but not negative about your problems)?	☐	☐	☐	☐	☐
Explaining things clearly (fully answering your questions, explaining clearly, giving you adequate information; not being vague)?	☐	☐	☐	☐	☐
Helping you to take control (exploring with you what you can do to improve your health yourself; encouraging rather than "lecturing" you)?	☐	☐	☐	☐	☐
Making a plan of action with you (discussing the options, involving you in decisions as much as you want to be involved; not ignoring your views)?	☐	☐	☐	☐	☐

INTERACTIONS WITH YOUR DOCTOR (JSPE-5)

Q47.

Answer the questions in this section about the DOCTOR WHO USUALLY PROVIDES MEDICAL CARE FOR YOUR LOW BACK PAIN. Do not consider other doctors when answering these questions.

IRB APPROVED

Q48. The doctor ...

AUG 07 2018

**NORTH TEXAS REGIONAL IRB
UNT HEALTH SCIENCE CENTER**

	Strongly agree	Agree	Uncertain	Disagree	Strongly disagree
Understands my emotions, feelings, and concerns.	☐	☐	☐	☐	☐
Seems concerned about me and my family.	☐	☐	☐	☐	☐
Can view things from my perspective (see things as I see them).	☐	☐	☐	☐	☐
Asks about what is happening in my daily life.	☐	☐	☐	☐	☐
Is an understanding doctor.	☐	☐	☐	☐	☐

INTERACTIONS WITH YOUR DOCTOR (PSQ-18)

Q49.

Answer the questions in this section about the DOCTOR WHO USUALLY PROVIDES MEDICAL CARE FOR YOUR LOW BACK PAIN. Do not consider other doctors when answering these questions.

Q50. How strongly do you AGREE or DISAGREE with each statement below?

	Strongly agree	Agree	Uncertain	Disagree	Strongly disagree
The doctors is good about explaining the reason for medical tests.	☐	☐	☐	☐	☐
The doctor's office has everything needed to provide complete medical care.	☐	☐	☐	☐	☐
The doctor's medical care I have been receiving is just about perfect.	☐	☐	☐	☐	☐
Sometimes the doctor makes me wonder if their diagnosis is correct.	☐	☐	☐	☐	☐
I feel confident that I can get the medical care I need from the doctor without being set back financially.	☐	☐	☐	☐	☐
When I go for medical care, the doctor is careful to check everything when treating and examining me.	☐	☐	☐	☐	☐
I have to pay for more of my medical care from the doctor than I can afford.	☐	☐	☐	☐	☐
I have easy access to the medical specialists I need through the doctor.	☐	☐	☐	☐	☐
At the doctor's office, people have to wait too long for emergency treatment.	☐	☐	☐	☐	☐
The doctor acts too businesslike and impersonal toward me.	☐	☐	☐	☐	☐
The doctor treats me in a very friendly and courteous manner.	☐	☐	☐	☐	☐
The doctor sometimes hurries too much when they treat me.	☐	☐	☐	☐	☐
The doctor sometimes ignores what I tell them.	☐	☐	☐	☐	☐

IRB APPROVED

AUG 07 2018

**NORTH TEXAS REGIONAL IRB
UNT HEALTH SCIENCE CENTER**

	Strongly agree	Agree	Uncertain	Disagree	Strongly disagree
I have some doubts about the ability of the doctor who treats me.	☐	☐	☐	☐	☐
The doctors usually spends plenty of time with me.	☐	☐	☐	☐	☐
I find it hard to get an appointment for medical care right away at the doctor's office.	☐	☐	☐	☐	☐
I am dissatisfied with some things about the medical care I receive from the doctor.	☐	☐	☐	☐	☐
I am able to get medical care whenever I need it from the doctor.	☐	☐	☐	☐	☐

INTERACTIONS WITH YOUR DOCTOR (JPSM-10)

Q51. Answer the questions in this section about the DOCTOR WHO USUALLY PROVIDES MEDICAL CARE FOR YOUR LOW BACK PAIN. Do not consider other doctors when answering these questions.

Q52. How strongly do you AGREE or DISAGREE with each statement below?

	Strongly agree	Agree	Somewhat agree	Uncertain	Somewhat disagree	Disagree	Strongly disagree
I am satisfied that my doctor has been taking care of me.	☐	☐	☐	☐	☐	☐	☐
The doctor explains the reason (s) for any medical test.	☐	☐	☐	☐	☐	☐	☐
The doctor explains things in a way that is easy for me to understand.	☐	☐	☐	☐	☐	☐	☐
I am confident of the doctor's knowledge and skills.	☐	☐	☐	☐	☐	☐	☐
The doctor shows respect to what I have to say.	☐	☐	☐	☐	☐	☐	☐
The doctor listens carefully to me.	☐	☐	☐	☐	☐	☐	☐
The doctor really cares about me as a person.	☐	☐	☐	☐	☐	☐	☐
The doctor encourages me to talk about my health concerns.	☐	☐	☐	☐	☐	☐	☐
The doctor spends enough time with me.	☐	☐	☐	☐	☐	☐	☐
I would like the doctor to be present in any emergency medical situation.	☐	☐	☐	☐	☐	☐	☐

IRB APPROVED

AUG 07 2018

**NORTH TEXAS REGIONAL IRB
UNT HEALTH SCIENCE CENTER**

Do You Have Low Back Pain?

We invite you to join our research registry for people with low back pain.

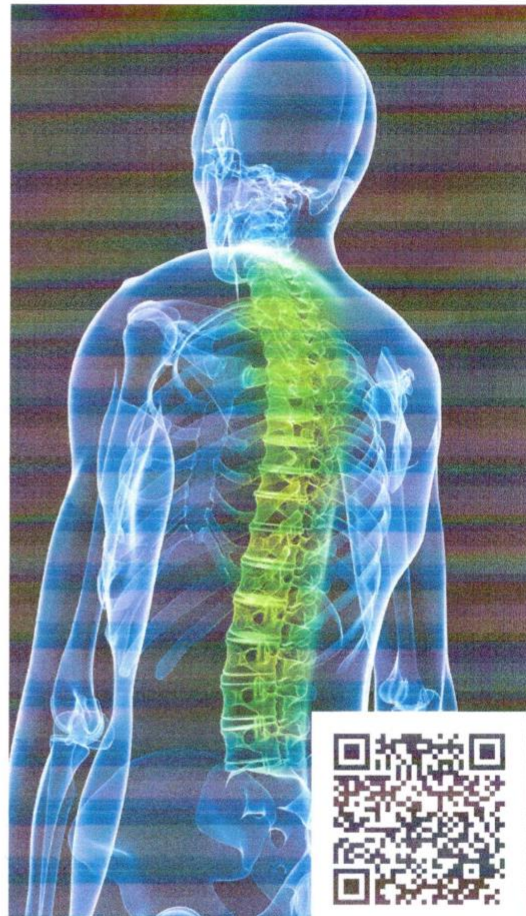
To enroll in the registry, known as PRECISION TEXAS, you will be asked to answer questions approximately every three months. You will also be asked to provide one-time saliva and blood samples for analysis of DNA, proteins and other biological substances.

If you qualify to participate, there will be an initial visit to the University of North Texas Health Science Center campus in Fort Worth's Cultural District. Regular follow-ups will be conducted in person, by telephone or online. You will be compensated for your time and travel. You must be between the ages of 21 years and 79 years, and may not be pregnant to enroll in this registry.

To learn more, please call 817-735-5410, or email us at orcstudyoperations@unthsc.edu.

You may also visit https://unt.az1.qualtrics.com/jfe/form/SV_6R4zT35wmifbVQN to complete a screening form to determine if you qualify for the registry.

We look forward to hearing from you.



IRB APPROVED

AUG 07 2018

NORTH TEXAS REGIONAL IRB
UNT HEALTH SCIENCE CENTER

UNT | HEALTH
SCIENCE CENTER
THE OSTEOPATHIC RESEARCH CENTER
Where Science Meets Practice

Initial Contact Script

IRB APPROVED

PRECISION TEXAS
Initial Contact Script

AUG 07 2018

**NORTH TEXAS REGIONAL IRB
UNT HEALTH SCIENCE CENTER**

**Coordinator: Use this script if the prospective subject contacts us regarding passing the online screening.*

Hello, may I speak with _____

My name is _____ calling from the PRECISION TEXAS Pain Research Registry at the UNT Health Science Center. You recently completed our online screening form and I am calling to set up your initial appointment.

The first visit will take up to three hours. During this visit, you will be asked to provide saliva and blood samples. You do not need to be fasting prior to providing these samples.

What date and time are best for you to complete this visit?

(Coordinator will coordinate appointment with study calendar)

Appointment Date & Time:

We are located at the UNT Health Science Center at:

**855 Montgomery St.
Fort Worth, Texas 76107**

When you enter the Patient Care Center, take the elevators located on the main floor up to the 4th floor. Upon exiting the elevators please enter the doors on the right to the waiting area and let the staff at the front desk know you are there for your appointment with the PRECISION TEXAS Pain Research Registry. Parking is available directly behind the building on Clifton Street.

When you come for your appointment please remember to bring the following two things: an original, valid, government-issued identification card that includes your photo and birthdate; and the medications that you take for low back pain or a list of those medications. If you do not take medication for low back pain, you will be asked to sign a form to certify this information. If you do not bring this information to your appointment, we will not be able to enroll you in the registry or compensate you for your time and travel. Please be prepared to complete an IRS W-9 form that includes your social security number as this will be required to compensate you for participating in the study.

If you have any questions before your appointment, please feel free to call me at _____

Revised 06/26/2018

Participant Withdrawal

IRB APPROVED

Subject ID#: _____

AUG 07 2018

**NORTH TEXAS REGIONAL IRB
UNT HEALTH SCIENCE CENTER**

I wish to withdraw my participation in the PRECISION TEXAS research registry.

I understand that I will not be contacted about this registry study or any future studies connected to this registry if I withdraw.

_____ I agree to continue to allow my information, saliva and blood samples collected up to this point to be used.

*(Please note if subject is notifying coordinator of withdrawal from study by phone, please note below. If the subject wishes to also withdraw her or his information, saliva and blood samples, the subject **MUST** provide a written request as outlined in the consent form.)*

(Subject Signature)

(Date)

(Coordinator Signature)

(Date)

(Notified by Phone)

(Coordinator's Initials)

(Date)

Flagged in Database: _____
(Coordinator's Initials)

(Date)

Revised 06/26/2018

APPENDIX D: Internship Activity Daily Log

Week 1

5/29/18

- Learned about protocol of study
- Learned how to use enrollment log and schedule subjects
- Learned how to register Clincard
- Worked on research proposal idea

5/30/18

- Worked on developing proposal idea
- Shadowed a 6-month subject visit
- Mailed clincards

5/31/18

- Continued to develop possible research topic
- Came up with questions/aims for proposal based on Qualtics survey questions
- Looked up previous PTX research/publications

6/1/18

- Research proposal day, reviewed literature of possible topic idea

Week 2

6/4/18

- Greenphire ID issued- was able to start registering Clincards to subjects
- Attended practicum workshop with fellows
- Shadowed 6-month subject visit and 2 baseline visits

6/5/18

- Met with Dr. Licciardone to discuss possible proposal ideas
- Worked on presentation for 1st committee meeting

6/6/18

- First committee meeting
- Topic changed, reviewed literature

6/7/18 and 6/8/18

- Logged missed visits/ lost to follow up subjects
- Scanned subject paper charts into electronic system
- Created IPS charts for new subjects
- Shadowed baseline visit and scanned in chart

Week 3

6/11/18

- Organized follow up and baseline folders for today's subjects
- Completed baseline visit
- Completed 6-month visit
- Attended practicum workshop with fellows

6/12/18

- Organized folders for today's subjects

- Learned how to fill out appointment reminder and document in new contact log
- Scheduled subjects and sent re-consent emails all afternoon

6/13/18

- Completed 3 month in person and 3-month phone visits
- Learned how to compensate with e-giftcard (subject lost clincard)
- Meeting with Dr. Licciardone
- Meeting with Dr. Dory to discuss new proposal idea and limitations of study

6/14/18

- Logged missed visits and scheduled subjects
- Worked on proposal
- Made new baseline folders
- Completed baseline visit

6/15/18

- Made new baseline folders and printed paperwork for next week's subjects
- Completed 18-month phone visit
- Dropped off internet ad at IRB for approval
- Learned about reporting Serious Adverse Events

Week 4

6/18/18

- Made reminder calls for Tuesday and Wednesday
- Completed 2 baseline visits and 1 follow up visit
- Called to schedule/re-consent subjects due for appointments

6/19/18

- Completed 3 baseline visits
- Completed 21-month phone visit
- Made reminder calls for Thursday

6/20/18

- Scanned in 3 paper charts into computer
- Made reminder calls for Friday
- Completed baseline visit
- Shadowed an IPS phone visit
- Worked on proposal during lunch

6/21/18

- Prepared subject folders for auditing- stopped at #117
- Tallied PRECISION TEXAS subjects by gender/race/ethnicity for IRB forms
- Precision Texas Meeting
- Completed 2 in person follow up visits
- Made reminder calls for Friday

6/22/18

- Prepared folders for auditing- stopped at #224
- Completed baseline visit and 15 month follow up visit
- Completed IPS wk 3 phone visit
- Made reminder calls for Tuesday

Week 5

6/25/18

- Prepared rest of folders for auditing
- Completed 9 month and 15 Month phone visits
- Had to reschedule 2 IPS visits
- Made reminder calls for Tuesday
- Printed new subject paperwork for the week
- Tallied IPS subjects by gender/race/ethnicity for IRB forms

6/26/18

- Completed 1, 12-month and 2, 24-month visits
- Completed baseline visit
- Completed IPS phone visit
- Made reminder calls for Thursday
- Made blood/saliva kits for baseline subjects

6/27/18

- Completed baseline visit
- Made reminder calls for Thursday and Friday
- Completed 3-month and 12-month visits
- Sent final draft of research proposal to committee
- Made saliva/blood kits for baseline subjects

6/28/18

- Edited final draft with suggestions from Dr. Jones and resubmitted
- Completed 3-month phone visit
- Completed in person IPS wk 1 visit
- Completed 12 month/24 month visits, and baseline visit
- Made reminder calls for Friday for those that did not already confirm
- Called 10 passed screenings to give more info about study and see if like to enroll

6/29/18

- Completed 3 baseline visits
- Completed 2, 12-month visits
- Made reminder calls for Tuesday
- Submitted final proposal
- Submitted committee paper work for CRM degree

Week 6

7/2/18

- Prepared folders for today's subjects
- Completed 2 baseline visits
- Made reminders for Tuesday if subj didn't confirm
- Printed all forms for this week's subjects
- Trenten showed me how to send links for IPS and document

7/3/18

- Completed baseline visit
- Completed IPS week 3 phone visit

- Farewell luncheon/PRECISION TEXAS MEETING
- Made reminder calls for Thursday
- Called to schedule those due for appt in July

7/4/18 Office Closed

7/5/18

- Completed 2 baseline visits
- Made reminder calls for Friday
- Called to schedule those due for appointment in July
- Qualtrics account working- exported subject surveys to pdf
- Sent emails with new consent V10 and W9 to subjects

7/6/18

- Compensated IPS subjects and pdf-ed surveys
- Updated enrollment log
- Completed 21 month in person visit
- Completed IPS wk 2 and PTX 9-month phone visit
- Made reminder calls for Monday and Tuesday

Week 7

7/9/18

- Made reminder calls for Wednesday
- Completed 15-month phone visit and 3-month phone visit
- Made saliva/ blood kits
- Completed IPS week 3 phone visit
- Printed all needed documents for the week
- Called qualified screenings to give more information/enroll
- Completed baseline visit
- Learned how to set up quest appointment for subject blood draw

7/10/18

- Prepared folders for today's subjects
- Completed 1 baseline visit, 1 no show
- Emailed baseline visit info to Wednesday subject
- Made Reminder calls for Thursday
- Completed 1 in person 6-month visit

7/11/18

- Prepared 2 baseline folders
- Made reminder calls for Friday
- Completed baseline visit
- Completed 9-month phone visit

7/12/18

- Assembled new baseline folders
- Made reminder calls for Friday
- Completed in person IPS wk 3 visit
- Completed Baseline visit

- Completed IPS phone visit

7/13/18

- Made reminder calls for Monday and Tuesday
- Completed 24-month in person visit w re-consent
- Completed 9 month in person visit
- Scheduled follow ups
- Completed baseline visit

Week 8

7/16/18

- Made Reminder Calls for Tuesday and Wednesday
- Completed IPS week 4 phone visit
- Completed 12-month in person visit
- Assembled new baseline folders and saliva/blood sample kits

7/17/18

- Completed 2 baseline subject visits
- Completed an in person 15-month visit
- Made reminder calls for Thursday

7/18/18

- Made reminder calls for Friday
- Completed baseline visit
- Completed a 3 month in -person visit
- Worked on thesis, literature research
- Turned in Intent to graduate

7/19/18

- Precision Texas meeting
- Completed IPS phone visit
- Completed In person 12 month visit w re-consent
- Called subjects to schedule for August follow-ups
- Screened subject and scheduled baseline visit

7/20/18

- Completed 2 baseline visits
- Made Reminder calls for Monday and Tuesday
- Called to schedule follow-up appointments for all odd numbered subjects
- Called screenings that qualified to give more info about study and enroll

Week 9

7/23/18

- Made reminder calls for Wednesday
- Completed IPS week 2 phone visit
- Completed 3 baseline visits

7/24/18

- Completed 2, 15 Month phone visits
- Assembled new Baseline folders and made saliva/ blood kits

- Made reminder calls for Thursday
- Rescheduled Baseline appt and made new quest appointment

7/25/18

- Assembled new baseline folders and made saliva/kits
- Made reminder calls for Friday
- Completed an 18 month in person visit
- Completed 2 baseline visits
- Attended STARS meeting- presentation of Greenphire payment system for subject compensation

7/26/18

- Completed 6-month phone visit
- Completed baseline visit
- Rescheduled 24-month phone visit
- Called to schedule follow up appointments
- Assembled new baseline folders and blood/saliva kits

7/27/18

- Completed 24-month phone visit
- Completed baseline appointment
- Made reminder calls for Monday and Tuesday

Week 10

7/30/18

- Completed 27-month survey visit
- Completed 2 baseline visits
- Made reminder calls for Wednesday
- Completed IPS Wk 3 phone visit

7/31/18

- Made blood/saliva kits
- Completed baseline visit
- Completed 24-month phone visit
- Made reminder calls for Thursday

8/1/18

- Completed in person 18-month visit
- Made reminder calls for Friday
- Worked on Thesis in the morning- Subject had to reschedule due to illness
- Completed Baseline visit
- Completed Week 1 IPS in person visit

8/2/18

- Worked on thesis in the morning
- Updated enrollment log with subjs still needing to enroll into IPS
- Updated Clincard disbursement log
- Completed 9 month in-person visit
- Completed baseline visit

8/3/18

- Made reminder calls for Monday and Tuesday
- Replenished fliers in Health Pavilion waiting rooms
- Completed 3 baseline visits

Week 11

8/6/18

- Completed 3 Baseline visits
- Completed IPS week 4 phone visit
- Made reminder calls for Wednesday

8/7/18

- Completed 2, 3 month PTX phone visits and 3 week IPS phone visit
- Made reminder calls for Wednesday for those that didn't confirm
- Completed 2 baseline visits

8/8/18

- Completed 3-month and 15-month phone visits
- Completed Baseline visit
- Made Reminder Calls for Friday
- Made new Baseline folders and blood/saliva kits

8/9/18

- Back-to-School Round-up event
- Transcribed paper screenings from event to electronic database

8/10/18

- Completed 12-month phone visit
- Completed Baseline visit
- Made reminder calls for Monday and Tuesday
- Made new baseline folders with new IRB approved documents

Week 12

8/13/18

- Made new baseline folders with newly approved IRB documents
- Made reminder calls for Wednesday
- Completed 2 baseline visits

8/14/18

- Completed IPS wk 1 phone visit
- Made reminder calls for Thursday
- Completed 2 baseline visits
- Completed 3-month phone visit
- Made new baseline folders and saliva kits

8/15/18

- Completed 3 baseline visits
- Made reminder calls for Friday
- Called to schedule subjects due for September visits

8/16/18

- Med School Interview Day

8/17/18

- Made reminder calls for Monday and Tuesday
- Completed 2 phone visits
- Made new baseline folders and blood/saliva kits
- Called to schedule subjects due for September visits

Week13

8/20/18

- Made reminder calls for Tuesday and Wednesday
- Completed 2 Baseline visits
- Completed IPS week 2 phone visit
- Completed 27-month phone visit

8/21/18

- Completed baseline visit
- Made reminder calls for Wednesday and Thursday
- Completed 2 IPS in person visits
- Completed 6-month phone visit
- Assembled new baseline folders and saliva/blood kits
- Recruitment
- Helped make FAQ for remote consenting

8/22/18

- Made reminder calls for Friday
- Started making folders for control subjects
- Sent PTX survey links out for online visits
- Scheduled subjects due for visit in September

8/23/18

- Completed baseline visit
- Helped make flow chart for process of remote consenting
- Made control and baseline folders and blood/saliva kits

8/24/18

- Made reminder calls for Monday and Tuesday
- Completed 3 baseline visits

Week 14

8/27/18

- Completed 2 baseline visits
- Completed IPS phone visit
- Called subjects due for September visit
- Meeting with IT about remote consenting/ developing new data management program

8/28/18

- Made new baseline folders and blood/saliva kits
- Made reminder calls for Thursday
- Completed IPS Phone visit
- Completed 9-month phone visit
- Called to schedule subjects due in September

8/29/18

- Made reminder calls for Friday
- Completed 3 baseline visits

8/30/18

- Completed baseline visit
- Called to schedule subjects due for September visits and emailed new consent documents
- Compensated online visits
- Made reminder calls to subjects for online surveys due by Friday

8/31/18

- Completed 2 baseline visits
- Made reminder calls for Tuesday

Week 15

9/3/18

- LABOR DAY- Office Closed

9/4/18

- Made reminder calls for Wednesday and Thursday
- Completed baseline visit
- Scheduled baseline
- Completed 3 IPS phone visits

9/5/18

- Made reminder calls for Thursday and Friday
- Completed baseline visit
- Completed 9-month phone visit
- Completed IPS phone visit
- Completed HS control visit

9/6/18

- Prepared supplies for recruitment event
- Printed out documents for baseline folders
- Completed 12-month phone visit
- Completed IPS phone visit
- Worked on Thesis

9/7/18

- Made reminder calls for Monday and Tuesday
- Completed 2 baseline visits
- Completed 21-month phone visit
- Called to enroll Health Status subjects that passed screening

9/8/18

- Roger Evans Community Center Back to School Event

Week 16

9/10/18

- Made Reminder calls for Wednesday
- Completed 2 IPS phone visits
- Completed 2 baseline visits

- Scheduled 2 HScontrol visits

9/11/18

- Completed 2 Health Status Baseline visits
- Completed 2 IPS phone visits
- Completed 6 month in person visit w re-consent
- Made reminder calls for Wednesday and Thursday
- Called Health Status passed screenings to give info about study/enroll subject

9/12/18

- Made reminder calls for Friday
- Checked HS voicemail and filed online HS completed screenings
- Sent online survey links for scheduled subjects
- Completed 9 month in person visit w re-consent paperwork
- Completed baseline visit

9/13/18

- Filtered through HS screening and called to enroll those who qualified
- Scheduled subjects due for October quarterly visit
- Completed baseline visit
- Completed annual RCOI training

9/14/18

- Made reminder calls for Monday and Tuesday
- Filtered through HS screening and called to enroll those who qualified
- Completed HS Control Visit
- Called to schedule those due for October Quarterly visit

Week 17

9/17/18

- Completed 6 and 12 month visits
- Completed 3 HS Baseline visits
- Made reminder calls for Tuesday and Wednesday
- Filtered through HS screenings and called to enroll passed screenings

9/18/18

- Completed 3 IPS phone visits
- Completed 21 Month in person visit with re-consent
- Called people from enrollment log to schedule next quarterly visit
- Called new HS screenings to enroll
- Made reminder calls for Thursday

9/19/18

- Made reminder calls for Friday
- Completed IPS phone visit
- Completed 24-month phone visit
- Completed 15 month in person visit with re-consent
- Training new coordinators-had students shadow for all phone/ in person visit and explained process

9/20/18

- Completed 12-month in person visit
- Completed 18-month phone visit
- Went over student's scripts for in-person consenting to make sure she had all pertinent information
- Precision Texas Research Team Meeting
- Worked on Thesis

9/21/18

- Completed 2 HS control visits
- Made Reminder calls for Monday and Tuesday
- Scheduled subjects do for October visit
- Completed Baseline visit
- Training new coordinators-had students shadow for phone/in person visits and explained process

Week 18

9/24/18

- Completed 3 IPS phone visits
- Completed 27-month in person visit with student shadowing, reassigned new clincard to subject after she lost previous card
- Updated Greenphire excel spread sheet with student, showed how to record assigned Clincard token numbers to each subject
- Made reminder calls for Wednesday

9/25/18

- Completed HS Control visit
- Completed IPS phone visit
- Made reminder calls for Thursday
- Completed baseline visit
- Filtered through new Control screenings and called eligible participants to enroll
- Completed 9-month Phone visit

9/26/18

- Made reminder calls for Thursday and Friday
- Completed IPS Phone Visit
- Completed 3-month phone visit
- Completed 2 baseline visits

9/27/18

- Completed 2 baseline visits
- Completed 1 IPS phone visit and 1 IPS in person visit
- Completed 12 month in person with re-consent
- Called Control screenings that passed to schedule
- Had student log/complete paperwork for visits above and checked work
- Discussed with Mrs. Kearns of internship experience thus far and what else I would like to gain from experience and reviewed comments on thesis draft

9/28/18

- Completed 1 baseline visit

- Completed 2 control visits
- Completed in person 18-month visit with re-consent
- Had student log/complete paperwork for visits above and checked work
- Met with Dr. Dory to discuss thesis rough draft
- Discussed account balances/budgeting and process of cost transfer in AOA grant

Week 19

10/1/18

- Completed HS baseline visit
- Completed 3 IPS phone visits
- Made reminder calls for Wednesday

10/2/18

- Completed 1 baseline and 2 HS visits with students handling subject chart and rechecking their work
- Completed 12 month in person visit with re-consent
- Rescreened participant to see if still qualify due to several reschedules/passed time

10/3/18

- Completed IPS Phone visit
- Completed 21 month in person with re-consent and trained students on how to reissue new Clincard to subject after losing previous
- Completed baseline visit with newly hired coordinator shadowing
- Submitted intent to defend form to GSBS
- Made reminder calls for Friday

10/4/18

- Had student prepare bag with charts for morning visits and check to make sure all documents were in folder
- Observed student as she completed 21-month visit and assisted when needed
- Completed HS Control Visit
- Observed student as she completed 6-month visit and assisted when needed

10/5/18

- Personal day/worked on thesis

Week 20

10/8/18

- Sent Online IPS Survey links for Monday
- PDF-ed/logged surveys and compensated subjects once surveys completed
- Made Reminder calls for Tuesday and Wednesday
- Completed 4/5 IPS Phone Visits, observed student completed one
- Observed/assisted student in 24-month phone visit

10/9/18

- Sent Online IPS Survey links for Tuesday
- PDF-ed/logged surveys and compensated subjects once surveys completed
- Made Reminder calls for Thursday
- Completed 3-month phone visit

- Completed 2 IPS Phone visits
- Called to schedule subjects due for November visit

10/10/18

- Observed students complete 2 baseline visits
- Observed student complete 18-month visit
- PDF-ed/logged surveys and compensated subjects once surveys completed
- Checked students work and made changes
- Called to schedule subjects due for November visit

10/11/18

- Completed 12-month and 21-month visit with student
- Completed 12-month phone visit
- Completed IPS phone visit
- PDF-ed/logged surveys and compensated subjects once surveys completed
- Staff meeting

10/12/18

- Naval Fitness Expo recruitment event

Week 21

10/15/18

- Created additional data tables and figures
- Added additional background info/ references
- Sent draft with new tables and figures to Dr. Dory

10/16/18

- Re-read references and made sure I accurately paraphrased information
- Worked on Chapter 3 Internship experience
 - Implemented paragraph on genetic analysis done on site
- Scheduled meeting with Dr. Dory to go over additional changes needed

10/17/18

- Meeting with Dr. Dory to review errors in format and grammar/sentence structures
- Added information about psychosocial therapies for better understanding of topic
- Worked on refining table legends and sentence structures in Chapter 2
- Scheduled meeting with CAP writing support

10/18/18

- Meeting with CAP writing support
- Continued to refine Ch 2 of thesis
- Wrote abstract

10/19/18

- Sent abstract to Dr. Dory
- Completed 30-month phone visit
- Completed 2 baseline visits
- Made reminder calls for Monday and Tuesday
- Updated data drive folder with newly approved IRB documents
- Scheduled quest appointments for baseline visits

Week 22

10/22/18

- Completed IPS phone visit
- Sent all IPS online links for Monday
- PDF-ed all online surveys as they were completed and compensated subjects/ logged email completion
- Made reminder calls for Wednesday
- Picked up new IRB approved documents and scanned into server

10/23/18

- Completed 2 IPS phone visits
- Sent all Tuesday IPS online survey links
- PDF-ed all online surveys as they were completed and compensated subjects/ logged email completion
- Updated Greenphire Clincard log excel spreadsheet
- Completed 3-month phone visit

10/24/18

- PDF-ed all online surveys as they were completed and compensated subjects/ logged email completion
- Resent Monday IPS links to those that still didn't complete survey
- Completed IPS Phone visit
- Called to rescreen participants that previously screened but never enrolled
- Made email script for re-contact/rescreen to send to IRB for approval
- Remade IPS online encounters excel spreadsheet after all IPS documents disappeared from the server
- Worked on defense ppt presentation

10/25/18

- Completed IPS phone visit
- Resent Tuesday links that weren't completed
- Worked on defense power point presentation
- Transferred all missing information to IPS enrollment log once it was added back to server
- Rescanned all missing IPS electronic charts from online visits this week that disappeared

10/26/18

- Logged missed visit
- Sent reminder calls to last 2 pending IPS online surveys
- PDF-ed all online surveys as they were completed and compensated subjects/ logged email completion
- Made reminder calls for Monday
- Worked on defense power point presentation
- Updated IPS online encounters spreadsheet with new subjects for the coming week

