ABSTRACT

BACKGROUND: Technology continues to push different aspects of research forward, including new recruitment methods and updated data collection/management. More and more, researchers are beginning to use social media as a valid recruitment method. Studies are also moving toward more remote methods of consenting research subjects and data collection. Several studies were found to use only online recruitment methods and many showed that Facebook was an effective method [1]. With this shift toward more remote and more technologically advanced research, it is important to explore whether increasingly adding technology to research studies shifts the study population in a way that impacts outcome measures. Based on previous research, studies with mainly remote modes of recruitment and data collection have a younger, more educated and less diverse population [2] [3] [4].

HYPOTHESIS: (1) By relying on technology and fewer interpersonal interactions, the demographics of the study population will shift toward younger participants, increased employment status, higher education level, fewer minority participants, and gender will shift to a more even balance of males to females. (2) Changes in the population demographics that are driven by technology will also increase the SPADE cluster score (Sleep disturbance, pain, anxiety, depression, and low energy/fatigue). Specific Aims for both Hypothesis I and II include; (1)To examine the demographics of the study population and outcome variable scores when looking at technology-focused recruitment methods implemented at different points in the study. (2) To examine the difference in demographics and outcome variable scores when looking at effects of the recruitment method alone (without the time of enrollment consideration).

METHODS: Survey data from the baseline visit of 583 subjects in the PRECISON Pain Research Registry were used. The subjects were divided into groups based on changes in recruitment methods over the course of the study to evaluate how changes in primary recruitment

methods may have shifted the population. The same 583 subjects were also divided into two groups: traditional methods and online methods to evaluate the effect of recruitment methods alone on the population. Demographics and the SPADE score outcome variables were analyzed using chi-squared and t-test analysis to see if there was a significant change between the groups.

RESULTS:

For Aim 1, there were no statistically significant changes in the population demographics or the SPADE outcome measures with the only exception being gender. For gender, the proportion of females has significantly increased as the reliance on digital methods, such as online newsletters and social media, has increased. For Aim 2, comparing enrolled subjects who were recruited through traditional methods such as flyers in clinics and the community to subjects who were recruited through online vehicles regardless of when they enrolled in the study, there was a significant difference in every demographic except ethnicity. The online group showed a significantly younger, more educated, and less diverse population.

DISCUSSION:

Hypothesis I was not supported by Aim 1 but was supported by Aim 2. This means that over the course of the study time the population has not changed dramatically, possibly because a mix of traditional and online recruitment methods is still being used. However, the population that was recruited using online methods was significantly different than the population recruited through traditional methods. It is important to keep this in mind as the study moves forward. Hypothesis II was not supported by either aim. Aim 1 showed minimal changes and Aim 2 showed a trend rejecting this hypothesis. Currently, there is no data to support that technological advances would have an increase the outcome variable scores.

Remote Recruitment and Data Collection
and
Its Effect on Demographics and Outcome Variable Scores

Presented to Graduate Committee Members from the University of North Texas Health Science Center

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

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Fort Worth, Texas

REMOTE RECRUITMENT AND DATA COLLECTION

AND ITS EFFECT OF DEMOGRAPHICS

AND OUTCOME VARIABLE

SCORES

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CHAPTER I

INTRODUCTION

The six-month internship and project practicum were completed at the Osteopathic Research Center (ORC) in the Department of Family Medicine at the University of North Texas Health Science Center. The ORC is conducting a longitudinal research project focused on low back pain, titled Pain Registry for Epidemiological, Clinical, and Interventional Studies and Innovation (PRECISION Pain Research Registry). This research registry is the source of data for this project. Ms. Cathleen Kearns served as the site mentor for this project and Dr. Ladislav Dory as the major professor. Dr. John Licciardone served as a thesis mentor and Dr. Patricia Gwirtz as a member of the committee.

This internship project examined the hypothesis that the transition to progressively more remote modes of subject recruitment, remote consenting, and data collection with fewer interpersonal interactions with project staff changes the demographic variables of the study population. Changes are expected specifically in areas such as age, employment status, education level, gender, race and ethnicity. This project also examined the effect of a possible shift in the population demographics on the outcome variables, such as pain level and anxiety. Background information for this project looked at previous research studies with mainly remote modes of recruitment and collection. These studies had a younger, more educated, and less diverse population [2] [3] [4].

Survey data from the baseline visit of 583 subjects in the PRECISON Pain Research Registry were used. The subjects were divided into two groups based on changes in recruitment methods over the course of the study. As the research team transitioned to using social media and other online vehicles to expand the pool of potential subjects for the registry, interpersonal interaction with the research team continued to be reduced. Thus, a goal of this project was to assess the impact of technology on the characteristics of the study population over the course of the study,

and to evaluate how this shift in the study population may affect the outcome variables. Group 1 included subjects that enrolled prior to Facebook being implemented as a recruitment method, which was from April 5, 2016 through May 29, 2018. At this time, the study's primary mode of recruitment was paper flyers in the UNTHSC clinics and at a wide range of locations in the community. Other recruitment methods during this time included online newsletters and friend referrals. Group 2 included subjects that enrolled after Facebook was implemented as a recruitment method, which was from May 30, 2018 through April 19, 2019. In April 2019 the study was placed on hold in order to transition to a new consenting process and electronic data capture system. While Facebook became the primary source of recruitment, previous methods were still incorporated. Also, by implementing Facebook as the main source of recruitment, a majority of the screening forms were being completed online, which began to reduce interpersonal interactions between the research team and study subjects. Research staff members still spoke with participants by phone to schedule the baseline visit, and the baseline visit was still conducted in-person during this second recruitment phase. The original analysis also included a small group of subjects who enrolled just after the study transitioned to a new data management system, called REDCap Cloud, where all facets of the study, including informed consent (managed through DocuSign) and biological sample collection, are completed remotely with little to no interpersonal contact with study personnel. These participants are included in the overall number of subjects, but due to a programing delay, the sample size was too small to be considered for individual statistical analysis.

In order to assess the effects of the recruitment method alone (without the time of enrollment consideration), the same 583 subjects were also divided into two groups: traditional methods and online methods. Traditional recruitment methods include flyers or friend referrals, while online methods include social media or online newsletters.

Data from the baseline survey were used because that study encounter includes key outcome variables for this project such as subject demographic information (the NIH Minimum Dataset), and the PROMIS-29, which measures quality of life. A subset of the PROMIS-29 survey instrument, the SPADE cluster score, was also used to explore quality of life outcome measures that may be impacted by a higher reliance on online recruitment and consent methods. The SPADE cluster score focuses on five dimensions of quality of life including sleep disturbance, pain interference, anxiety, depression, and low energy/fatigue. All demographics and SPADE scores were compared across the groups.

CHAPTER II

RESEARCH PROJECT

BACKGROUND

Technology continues to push every aspect of our society forward, and research is no exception. Many research groups are shifting from traditional recruitment methods such as flyers and clinic recruitment to online and social media recruitment methods. Several studies were found to use only online recruitment methods with many of them finding that Facebook was an effective method [1].

There are over 2 billion Facebook users worldwide with 88% of them in the 18-29 age group and 82% being college graduates [5]. Texas has the second highest number of Facebook users in the country with 11 million users. California tops the list at 19 million Facebook users. [6]. With these numbers, there is no question that Facebook and other social media sites can be very useful recruitment tools. Specific benefits linked to using Facebook as a recruitment method include reduced cost per subject recruited, shorter recruitment time, better representation, and improved recruitment of hard to reach demographics. Facebook was shown to cost $14.41 per participant compared to $1,094.27 per participant for television advertisements and $811.99 per participant for print advertisements [7].

Not only is technology changing the way recruitment is managed for studies, it is also changing the way data are collected. Many studies are moving to remote data collection through technologies such as online surveys, wearable devices, and mobile applications. Locally, the PRECISION Pain Research Registry has been using online surveys to collect remote data for encounters after the baseline visit since its inception [8]. Elsewhere, Apple partnered with Stanford University School of Medicine to test the ability of the Apple Watch to detect atrial fibrillation. Data were collected remotely through the application on the watch and sent directly

to the research staff [9]. Another example is a study in which researchers created a mobile application for subjects to self-report back pain. In this study, the application provided each subject with a personalized action plan for pain prevention. The self-reported data were then sent to the research staff to see if there was improvement after the subject received the personalized action plans [2].

One potential issue with moving toward online recruitment and remote data collection is that population demographics may be skewed. Not all populations are comfortable using online technology or may not have access to it. This could cause a shift to a more educated, higher earning, technology savvy population. [10]. In the Irvine Study, where subjects were able to self-report back pain on the mobile application, the demographics in the treatment group were 58% female, 76% Caucasian, 37% with a college degree, 20% with some level of graduate school, and 72% employed full time [2]. In an additional study, heart patients and diabetic patients were given mobile phones with specific software that allowed them to track certain parameters once a week. The demographics of the treatment groups were 66% men in the heart patients and 51% men in the diabetic patients. The average age was 69 years of age for the heart patients and 66 years of age for the diabetic patients. Sixty-nine percent of all patients were retired. One interesting note in this study was that 8% of subjects withdrew from the study because of their lack of familiarity with the mobile phones [3]. Another study examined which people in the United States are using applications to monitor their health. In this study, it was reported that people who used a health application were younger, more likely to live in metropolitan areas, be more educated, and have a higher income. Fifty-one percent of the participants that used a health application were female, 65% were in the 18-44 age group, and only 12% had less than a college degree. Compared to the group that did not use a health application, 50% were female, 52% were in the 18-44 age group and 28% had less than a college degree. [4].

Outcome variables may also be affected by a change in the population demographics. Potentially, the new population could be a younger population that uses technology and social media more frequently. Multiple studies have shown that this tech-savvy population may have higher levels of anxiety, sleep disturbance, and depression. For example, young adults that had higher social media use had significantly greater odds of having a sleep disturbance [11]. Increased social media use has also shown to be significantly associated with anxiety symptoms, but not anxiety-related impairments [12]. In another study, social media use was shown to lead to higher odds of depression [13]. The variables in the SPADE cluster comprise five of the most prevalent chronic symptoms and they each have an effect on each other. For example, pain and depression occur together 30-50 percent of the time. Increased aggravated pain may lead to an increase in sleep disturbance. An increase in any one of the symptoms may increase another cluster symptom, which can negatively affect how patients respond to treatment as well as have an overall negative effect on the patient's general health. [14].

Problem

As a larger number of participants were enrolled into the registry, the recruitment area that supplies the study population became depleted. There is a limited number of people that can be recruited from one medical practice group, organization, location or a limited geographic region. Each of these transitions were driven by the need to increase the number of participants enrolled in the registry by recruiting from a larger geographic area. By switching from paper advertisements to social media, recruitment efforts were broadened to additional communities and target audiences in the DFW metroplex. By shifting to electronic consent and allowing all study encounters to be completed remotely, the study can reach participants from a wider geographic area including other cities in Texas. Managing all facets of enrollment and data

capture remotely also allows more participation by people who work full-time and who are not able to complete visits in person.

While many positives come out of moving to remote models, it is a concern that the demographics of the study population will change. Specific to this study, the demographics that are of concern are age, employment status, education level, race, ethnicity, and gender because it is important to have a study population that reflects the population of the state of Texas.

Changes in recruiting and data collection may also have an effect on outcome variables because of a potential shift in the enrolled population. The outcome variables that will be examined in this study include sleep disturbance, pain, anxiety, depression, and low energy/fatigue. These outcome measures are part of the SPADE cluster that is collected using the PROMIS-29 instrument.

SPECIFIC AIMS AND SIGNIFICANCE

Hypothesis I

By relying on technology and reducing interpersonal interactions, the demographics of the study population will shift toward younger participants, increased employment status, higher education level, fewer minority participants, and gender will shift to a more even balance of males to females.

Hypothesis II

Changes in the population demographics that are driven by technology will also increase the SPADE cluster score (Sleep disturbance, pain, anxiety, depression, and low energy/fatigue).

Aim 1

To examine the demographics of the study population and outcome variable scores when examining technology-focused recruitment methods implemented at different points in the study.

Aim 2

To examine the difference in demographics and outcome variable scores when looking at effects of the recruitment method alone (without the time of enrollment consideration).

Significance

The major advancements for the PRESICION Pain Research Registry that will allow the study to transition to a state-wide registry consist of the transition to Facebook advertising, data collection within REDCap and DocuSign for remote consenting. However, it is important to know what effect this transition will have on the data that are collected. Study population demographics should be representative of the recruitment region for the study. Registry projects specifically need similar baseline demographics to the population that they are supposed to be representing in order for the data to be generalizable [15]. With the intention of becoming a state-wide registry, the demographics of the registry should be similar to those of the state. When a change in the data collection methodology and a significant expansion of the recruitment area occurs, it is important to examine the impact.

EXPERIMENTAL DESIGN: METHODS AND MATERIALS

Data Collection

Data were used from the PRECISION Pain Research Registry. The registry collects data quarterly following the baseline visit. This project used data from the screening form, the baseline visit, and the ORC Facebook page. The majority of data analyzed for Aims 1 and 2 were collected at in-person visits using an online survey tool (Qualtrics). During these in-person visits, participants either completed the survey using a computer or responded as each question was read to them by a research team member, who then entered the response for them. A small portion of subjects completed the survey through REDCap Cloud, which is the new system, but the survey questionnaires are the same as previously deployed using Qualtrics.

Population

The population for the PRECISION Pain Research Registry inclusion criteria consists of subjects between the age of 21-79 years of age that have had low back pain for at least 2 months and have pain at least half the days over the last 2 months. Subjects also must have had a doctor that provides medical care for their low back pain for at least 1 month. Exclusion criteria includes subjects who are pregnant, incarcerated or institutionalized. In addition, subjects must be able to understand forms in English as no translation services are provided. It should be noted that as of August 2019, two aspects of the inclusion criteria for the PRECISION Pain Research Registry changed to only include subjects with low back pain for 3-6 months and they must have pain for at least half the days of the last 6 months.

Survey Elements and Instruments

The baseline survey is made up of several well-validated survey instruments including the National Institutes of Health (NIH) minimum dataset for low back pain, history of medical conditions, low back pain-specific opioid use, low back pain-specific nonsteroidal anti-inflammatory drug use, history of nonpharmacologic treatments for low back pain inventory, numerical rating scale for low back pain, Roland-Morris Disability Questionnaire, Patient-Reported Outcomes Measurement Information System (PROMIS 29), pain sensitivity questionnaire, pain catastrophizing scale, pain self-efficacy questionnaire, communication and behavior questionnaire, consultation and relational empathy measure, patient satisfaction questionnaire, and patient satisfaction with the primary care physician. For the purposes of this study, the specific instruments that were used were the NIH Minimum Dataset for low back pain and the PROMIS 29. The NIH Minimum Dataset relates to subject demographics and is used with participants with either subacute or chronic low back pain. PROMIS 29 measures quality of

life. A subset of the PROMIS-29 will show a subject's SPADE score, which focuses on five dimensions of quality of life [8].

NIH Minimum Dataset

The NIH Minimum Dataset included questions related specifically to low back pain as well as overall pain intensity and general demographic questions. Demographic questions were self-reported by subjects as follows: age - subjects input freely; gender - the answer choices were male and female; race - subjects were asked to select one they most closely identified with and the options were American Indian/Alaskan Native, Asian, Black or African American, Native Hawaiian or other Pacific Islander, and White; and ethnicity - subjects were also asked to select one option that they most closely identified with between Hispanic/Latino or Not Hispanic/Latino. Subjects were asked to choose the highest education level attained from the following options: No high school diploma, high school graduate/GED, Some college (no degree), occupational/technical/vocational program, associate's degree, bachelor's degree, master's degree, professional school degree (e.g. physician, dentist, attorney), or doctoral degree (e.g. PhD). Lastly, for employment status, subjects could select one of the following options: working now, looking for work/unemployed, sick leave/maternity leave, disabled due to back pain (permanently or temporarily), disabled for reasons other than back pain, student, temporarily laid off, retired, keeping house, or other.

PROMIS-29- SPADE Cluster

The SPADE cluster score is generated from sections of the PROMIS 29 instrument. For each domain of the SPADE score (Sleep disturbance, pain interference, anxiety, depression, and low energy/fatigue) four questions are asked. Each question has five choices to rank their current symptoms scoring from 1-5, so each subset can range from a raw score of 4-20. The scored for

each domain are reported as T-Scores, which standardizes the raw score to a t-score with a mean of 50 and a standard deviation of 10. The overall SPADE score can range from 20-100.

Analysis

Data from the screening database were used to analyze the methods of recruitment that subjects disclosed on their screening form. Data from the ORC Facebook page were also used in order to look at how three different ads performed in terms of subject engagement. Demographics for this project came from the NIH Minimum Dataset and the SPADE scores were derived from the PROMIS 29 questionnaires. Descriptive analysis was completed through the SAS statistical software for all continuous and categorical variables. For the continuous variables, such as age and SPADE scores, the mean scores and standard deviations were calculated. For the categorical variables, frequency and percentages were calculated. SAS was also used to complete t-tests for continuous variables and chi-squared analysis for categorical variables. All tests for statistical significance were based on a P-value of 0.05.

RESULTS

Screening Data

Screening data came from the PRECISION screening database located in REDCap Cloud. (Please note that all screening and registry data were migrated into REDCap Cloud during the transition period, so all 583 currently enrolled subjects are represented in REDCap Cloud.) On the screening form, subjects disclosed how they heard about this research study. That information was used to show how many people were screened from each recruitment method. Then, the number of subjects that passed and the number of subjects that enrolled in the study were calculated for each recruitment type. Overall, there were eight main sources of recruitment. These include UNTHSC clinics, Facebook/social media, other online sources, community flyers, newspaper advertisements, friend referrals, UNTHSC Daily News, and wellness fairs. Figure 1 shows the breakdown of each recruitment method including how many screening forms were completed, how many subjects passed, and how many enrolled from each recruitment source. Overall, the three largest sources of recruitment came from Facebook/social media, other online sources, and friend referrals. The source with the best retention rate for a subject continuing through the screening process to enrollment was recruitment from the UNTHSC clinics. The City of Fort Worth employee newsletter and a few other sources such as the UNTHSC website and local school district newsletters were the largest source of recruitment for Group 1 (pre-Facebook), which is shown in Figure 1 as other online recruitment methods. Group 2 (post-Facebook) shows Facebook/social media as their largest sources of recruitment. Facebook and social media show the lowest proportion of subjects that complete the enrollment process after screening. Currently, Facebook and social media are the largest sources of recruitment.

Figure 1:Recruitment Breakdown

Facebook Data

Facebook data came from the ORC Facebook page. From the time that Facebook was used as one of the primary recruitment methods, 40 posts have been made and $2,500 has been spent on Facebook advertisements. Three different recruitment posts were evaluated for this study: the posts were dated August 24, 2017, August 31, 2018, and August 17, 2019. The post from August 24, 2017 was the first Facebook advertisement that provided a direct link to the online screening form and the post from August 17, 2019 was the first Facebook advertisement after recruitment reopened following the transition to REDCap Cloud and DocuSign. These three advertisements were chosen because they were each posted at strategic time points in the study. Figure 2 shows how many people each of the three posts reached. Table 1 shows a breakdown of Facebook statistics for each of these three posts. The most recent post (August 17, 2019) reached over 19,000 people, the most of any advertisement thus far. The August 31, 2018 post had the highest number of clicks on the post, making it the most cost-effective advertisement of the three. Table 2 shows the percentage of screening forms and subjects enrolled from the total clicks on the advertisement. The most recent advertisement had 27% of those that clicked on the advertisement complete a screening form and 29% of those that filled out a screening form completed the online consent form. The advertisement from August 31, 2018 yielded a slightly higher percentage of completed screening forms (28.7%), but only 12% of those that completed a screening form enrolled in the study. Clicks are not necessarily a direct correlation to the number of screening forms completed, but that number does provide research staff members with a gauge of how the ad is performing.

Figure 2: Individual Facebook Post Reach

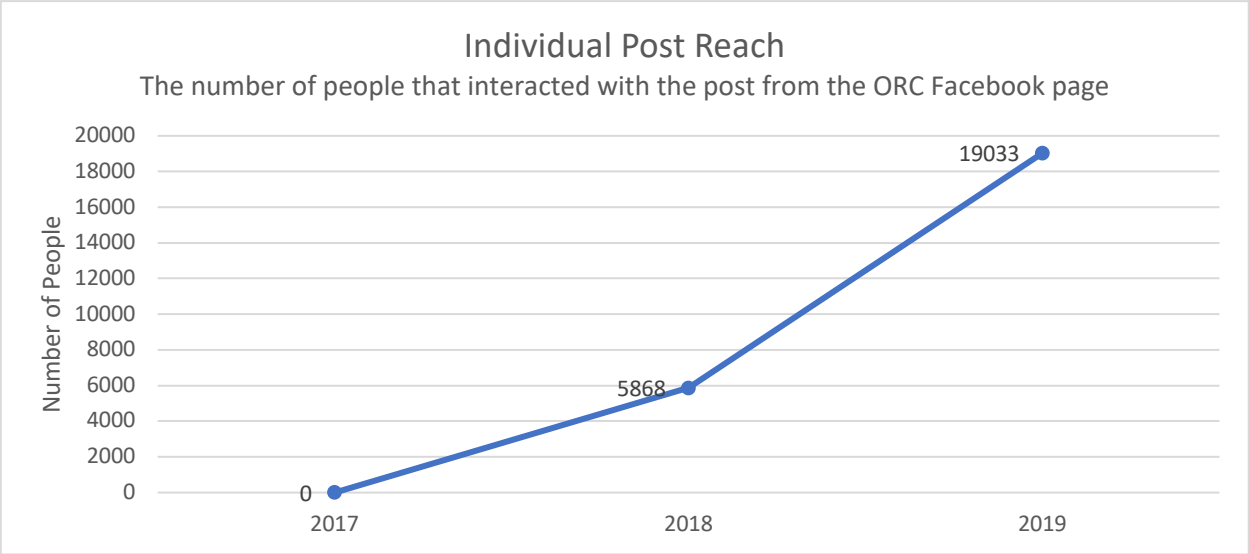

Table 1: Facebook Post Statistics

Individual post date	8/24/17	8/31/18	8/17/19
People reached	0	5868	19033
Likes/Comments/Shares	2	34	45
Post clicks	0	326	149
Link Clicks	0	87	111
Cost per link click	N/A	$1.15	$2.70
% Women	N/A	94.10%	81.60%
% Using Mobile Devices	N/A	96.10%	95.40%
Cost per ad	$0	$100	$200

Columns are categorized by individual Facebook posts. Rows are categorized by statistics from each post including how many people saw the post (reached by the post), how many interactions with the post (likes/comments), how many people clicked on the post, how many clicked on the link, the individual cost per link click, gender proportions, percentage of people that used a mobile device to interact with the post, and how much each individual advertisement cost.

Table 2: Number and Percentages of Screening Forms and Subjects Enrolled from Facebook

Date of post	Link Clicks (**n**)	Screening forms (n)	Signed Consent (n)	**Screened** from link clicks (%)	Enrolled from screening forms (%)
8/17/19	111	31	9	27.9	29.0
8/31/18	87	25	3	28.7	12.0
8/24/17	0	0	0	0	0

Rows are categorized by individual Facebook posts. Columns are categorized by statistics from each post including how many people clicked on the link, how many people filled out a screening form, how many people signed a consent form and then percentages based on those raw numbers.

Aim 1 Results

Baseline data were from the PRECISION database on REDCap Cloud. From the baseline data, the NIH Minimum Dataset and the PROMIS 29 sections were extracted for analysis. Table 3 contains the descriptive values and percentages of the demographics. The mean age was 54 years of age for Group 1 and 52 years of age for Group 2. The percentage of females was higher than males in both of the groups, as well as the percentage of Whites and Non-Hispanic/Latino compared to other race and ethnic groups. The majority of subjects were college educated and currently working. Also included in Table 3 are the percentages for the overall demographics for the State of Texas [16]. The Texas demographics are the standard for this study as it continues to grow to be a state-wide registry. Currently, Texas has a more proportional ratio of males to females and has a larger proportion of people that identify with the Hispanic/Latino ethnic group compared to the study population. However, in terms of racial groups, Group 2 of this study shows similar percentages for most racial groups. Currently, the PRECISION Pain Research Registry has a population with higher education levels compared to the State of Texas population.

There were no significant changes in the mean age between groups. The analysis for gender showed that there was a significant change in the ratio of males to females for Group 2 based on a P-value of 0.0002. This means that there is a higher number of females in Group 2. For race and ethnicity, employment status, and education level, there were only minor, non-significant changes between groups.

The overall SPADE score and the dimension scores that make up the overall SPADE score was from the PROMIS 29 dataset. This includes the sleep disturbance, pain interference, anxiety, depression, and low energy/fatigue scores. Table 4 shows the mean scores for each group. The overall SPADE score did not change much between the groups, ranging from 54-56.

The national average SPADE score is 50, so the averages for the overall SPADE score or each group in this study are slightly higher. There was no significant change in the overall SPADE scores or the sub-scores when comparing the groups.

Table 3: Demographics Descriptive Values and Percentages

Demographics	Overall		Group 1		Group 2		P-value	Texas Demographics
	n	%	n	%	n	%		
Total (N)	583*	–	304	–	265	–		28,701,845
Age							0.39	
Mean Age (years)	53±12	–	54±12	–	52±12	–		–
Gender							0.0002	
Male	176	30.2%	113	37.2%	60	22.6%		49.7%
Female	407	69.8%	191	62.8%	205	77.4%		50.3%
Race							0.43	
American Indian/ Alaskan Native	10	1.7%	6	2.0%	4	1.5%		1.0%
Asian	13	2.2%	9	3.0%	4	1.5%		5.3%
Black/African American	158	27.1%	90	29.6%	66	24.9%		14.8%
Native Hawaiian/ Pacific Islander	3	0.5%	1	0.3%	2	0.8%		0.1%
White	399	68.4%	198	65.1%	189	71.3%		78.8%
Ethnicity							0.13	
Hispanic/Latino	75	12.9%	45	14.8%	28	10.6%		39.6%
Not Hispanic/ Latino	508	87.1%	259	85.2%	237	89.4%		60.4%
Education							0.19	
High School or Less	138	23.7%	80	26.3%	53	20.0%		65.1%
College Educated	363	62.3%	185	60.9%	172	64.9%		26.0%
Graduate/ Professional Degree	82	14%	39	12.8%	40	15.1%		8.9%
Employment							0.53	
Working Now	227	38.9%	119	39.1%	101	38.1%		64%
Looking for work/ Unemployed	40	6.9%	21	6.9%	17	6.4%		3.4%
Disabled due to low back pain	71	12.2%	41	13.5%	29	10.9%		–
Disabled for other reasons	88	15.1%	51	16.8%	37	14.0%		–
Retired	93	16.0%	43	14.1%	46	17.4%		–
Other	64	11.0%	29	9.5%	35	13.2%		–

**14 subjects who enrolled after transition to REDCap Cloud are included in this overall total. Group one represents subjects enrolled during beginning phase of the study. Group 2 represents subjects enrolled after Facebook became the primary recruitment method. Texas demographics from the U.S Census bureau (16). Total sample size for Group1 and Group 2 are n=304 and n= 265, respectively. Rows are categorized by age, gender, race, ethnicity, education, and employment status Columns labeled n represents number per group and the columns labeled % represent the percentage of individuals per group in a designated category. Age (in year) is given as the mean age per group along with the standard deviation. P-values based on chi-squared analysis or t-test (for age).*

Table 4: SPADE Mean Scores

Mean Scores	Overall	Group 1	Group 2	P-value
SPADE	56.0±6.9	56.0± 7.1	56.1±6.7	0.96
Pain Interference	61.0±7.7	61.4±8.0	62.5±7.4	0.22
Anxiety	53.5±10.5	53.9±10.4	53.3±10.5	0.78
Depression	51.7±9.4	52.4±9.6	51.0±9.1	9.19
Low Energy/Fatigue	56.9±10.1	56.8±10.1	57.1±10.2	0.96
Sleep Disturbance	55.9±8.3	55.3±8.2	56.8±8.2	0.09

Group 1 represents subjects enrolled during beginning phase of study. Group 2 represents subjects enrolled after Facebook became the primary recruitment method. Total sample size for Group 1 and Group 2 are n=304 and n= 265, respectively. Rows are categorized by overall mean SPADE score, mean pain interference score, mean anxiety score, mean depression score, mean fatigue score, and mean sleep disturbance score. Columns are labeled by group category. The final column shows the p-value based on t-test analysis.

Aim 2 Results

Table 5 shows the results for comparing subjects recruited using traditional methods and subjects recruited using online methods. Traditional methods include flyers in the UNTHSC clinic, community flyers, friend/family referrals, newspaper ads, and wellness fairs. Online methods include Facebook and other social media such as Twitter or Google ads and online newsletters. Overall, when comparing online to traditional methods, there was a significant difference in the proportions of every demographic except ethnicity. The online group showed a significantly younger, more educated, and less diverse population. It also showed that there were more subjects who worked full-time and a lower percentage that were disabled. Gender also shifted to a higher proportion of females in the online group.

Table 6 shows the SPADE results for comparing subjects recruited using traditional methods and online methods. There were significant differences in the overall SPADE score and the pain interference, anxiety, and depression sub-scores. For all of these measures, the group of

subjects recruited using traditional methods showed significantly higher scores. Sleep disturbance and fatigue only showed minimal changes between groups. The overall SPADE score of both groups was above the national average of 50.

Table 5: Recruitment Source Proportions Traditional Methods vs. Online Methods

Demographics	Traditional		Online		P-Value	Texas Demographics
	n	%	n	%		
Total (N)	321	–	262	–		28,701,845
Age					<0.001	
Mean Age (years)	55±12	–	50±12	–		–
Gender					<0.001	
Male	128	39.9%	48	18.3%		49.7%
Female	193	60.1%	214	81.7%		50.3%
Race					<0.001	
American Indian/ Alaskan Native	7	2.2%	3	1.2%		1.0%
Asian	5	1.6%	8	1.4%		5.3%
Black/African American	117	36.5%	41	15.7%		14.8%
Native Hawaiian/ Pacific Islander	1	0.3%	2	0.8%		0.1%
White	191	59.5%	208	79.4%		78.8%
Ethnicity					0.86	
Hispanic/Latino	42	13.1%	33	12.6%		39.6%
Not Hispanic/ Latino	279	86.9%	229	87.4%		60.4%
Education					<0.001	
High School or Less	106	33.0%	32	12.2%		65.1%
College Educated	186	57.9%	177	67.6%		26.0%
Graduate/ Professional Degree	29	9.0%	53	20.2%		8.9%
Employment					<0.001	
Working Now	61	19.0%	166	63.4%		64%
Looking for work/ Unemployed	33	10.3%	7	2.7%		3.4%
Disabled due to low back pain	57	17.8%	14	5.3%		–
Disabled for other reasons	74	23.1%	14	5.3%		–
Retired	63	19.6%	30	11.5%		–
Other	33	10.3%	31	11.8%		–

Traditional represents subjects recruited using methods such as clinic/community flyers or friend referrals. Online represents subjects recruited using social media or other online methods such as Facebook or online newsletters. Total sample size for traditional and online are n=321 and n= 262, respectively. Rows are categorized by age, gender, race, ethnicity, education, and employment status 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 standard deviation. P-values based on chi-squared analysis or t-test (for age).

Table 6: SPADE Scores Traditional Methods vs. Online Methods

Mean Scores	Overall	Traditional	Online	P-value
SPADE	56.0±6.9	57.1± 7.5	54.7±7.1	<.0001
Pain Interference	61.0±7.7	63.1±8.2	60.4±7.7	<.0001
Anxiety	53.5±10.5	55.1±10.1	51.5±10.3	<.0001
Depression	51.7±9.4	53.6±9.7	49.3±9.3	<.0001
Low Energy/Fatigue	56.9±10.1	57.2±10.5	56.6±10.3	0.46
Sleep Disturbance	55.9±8.3	56.3±7.9	55.5±8.1	0.26

Traditional represents subjects recruited using methods such as clinic/community flyers or friend referrals. Online represents subjects recruited using social media or other online methods such as Facebook or online newsletters. Total sample size for traditional and online are n=321 and n= 262, respectively. Rows are categorized by overall mean SPADE score, mean pain interference score, mean anxiety score, mean depression score, mean fatigue score, and mean sleep disturbance score. Columns are labeled by group category. The final column shows the p-value based on t-test analysis.

DISCUSSION AND CONCLUSION

This study was designed to examine whether technological advances in recruitment methods and data collection affect the population of a longitudinal research study, and to determine if these potential changes in the population affect outcome variables of the study.

The recruitment data from the screening forms did show that once social media was introduced as a recruitment method, it quickly became one of the top recruitment methods used. The most interesting trend from this data was social media had the highest number of screening forms and subjects enrolled, it also had a large number of people who did not complete enrollment after passing the screening questionnaire. Social media accounted for a large number of subjects enrolled simply because it reached more people. Alternatively, subjects recruited from the UNTHSC Clinic had the highest number of subjects enroll after passing the screening. This could be due to familiarity with our organization or simply due to convenience for these subjects since they already visit the clinic.

With Facebook being the main source of recruitment, it was interesting to examine how the posts have been received by the public over the past few years. One of the very first Facebook marketing posts made by the ORC staff was in August of 2017. Comparing posts in August 2018 and 2019, there was a steady increase of post engagements including likes and clicks directly to the Facebook page or on the embedded screening link. The post in 2018 had a slightly higher percentage of screening forms from the Facebook post compared to 2019. This delay in numbers in 2019 could be due to Facebook changes made earlier this year in the advertisement algorithms. Since recruiting commenced again in August 2019, the PRECISION research team has worked directly with the Facebook marketing team to improve advertisements. Since becoming educated about the new Facebook process, the ORC staff has seen a large increase in post engagement.

When examining the results for Aim 1, in most cases, the demographics remained consistent from group to group with minimal changes in the frequencies with the exception of gender. There was a significant increase in the proportion of females to males in Group 2 of this study. This does not support my hypothesis of the gender ratio moving toward a 1:1 ratio of males to females. This is a surprising result based on the gender demographics of Facebook, of which 43% of users are females and 57% of users are males [5]. By comparing the demographics of Texas to those in this study, it can be seen that currently the PRECISION demographics are different in most categories. This is not a surprising result since enrollment for the entire state just opened in August 2019. This data can be used as the study moves forward to see what populations could be targeted that are not currently being reached. For the SPADE outcome variables, there was no significant change between the groups. There were slight changes in the mean scores for all variables, but not enough for the changes to be statistically significant.

When analyzing the data in Aim 2, most of the demographics did show a significantly different proportion when comparing traditional to online recruitment methods. Overall, the subjects recruited using online methods were younger, more educated and less diverse. There also was a higher percentage of subjects working in the online group as well as a lower percentage of subjects on disability. Gender shifted to a higher proportion of females to males. It is interesting to see that subjects recruited online do have many of the characteristics that were originally hypothesized. The SPADE outcome variables did show a significant difference between the subjects recruited through traditional methods and those recruited through online measures. The subjects recruited using traditional methods had significantly higher overall SPADE scores as well as higher pain interference, anxiety, and depression scores. This rejects my original hypothesis that a more technologically-advanced population would have higher SPADE scores. Many of the subjects recruited using traditional methods were recruited from the UNTHSC Clinic, and in general, many patients at the UNTHSC Clinic receive a portion of their income from disability payments. This could be one reason for the increased SPADE score due to the physical disability as well as the financial worry.

The purpose of this study was to determine whether changes in the recruitment method and data collection services would change the overall population of the study and if that would affect the outcome variables. Overall, Hypothesis I was not supported by Aim 1, but was supported by Aim 2. This means that over the course of this study, the population has not changed dramatically. However, the population that was recruited using online methods was significantly different than the population recruited from traditional methods. This could possibly be due to the fact that a mix of recruitment methods is still being used. By continuing to recruit from the community and the UNTHSC clinic, as well as the social media methods, the ORC staff is able to reach a larger, more diverse audience. This data could be used in future research to

target populations that are possibly being missed with the current online methods. Future research could also be done when there are more subjects recruited using remote consenting to see if this process has a great impact on the population. Hypothesis II was not supported by either aim. Aim 1 showed minimal changes over the course of the study and Aim 2 showed a trend rejecting this hypothesis. This is not a surprising result for Aim 2 because many of the traditional method subjects are enrolled out of the UNTHSC clinic or from food banks and churches in the community. Working one-on-one with some of these subjects, many of them are on disability income as well as have many medical problems they are dealing with on a daily basis. These are problems that can cause extra stress in their life that could cause an increase in the SPADE cluster scores. Overall, this study showed no data to support that technological advances would increase the outcome variable scores. As this study continues to grow and integrate technology, these are issues that the research staff should continue to assess.

CHAPTER III

INTERNSHIP EXPERIENCE

INTERNSHIP SITE

The internship for this program was completed with The Osteopathic Research Center (ORC) located at the University of North Texas Health Science Center in Fort Worth Texas. John Licciardone, DO, MS, MBA, serves as the executive director of the ORC as well as the principal investigator of the PRECISION Pain Research Registry. Cathleen Kearns is the research assistant director and Samantha Johnson is the lead research coordinator. Noah Hendrix was also a clinical research management intern and Vishruti Pandya is a graduate student research assistant. Nicole Phillips, PhD, serves as the director of genomic research for the ORC.

The ORC is currently working on the PRECISION Pain Research Registry (Pain Registry for Epidemiological, Clinical, and Interventional Studies and Innovation). This study plans to recruit up to 4,000 total subjects, with 2,000 having low back pain and 2,000 controls. The goal is to recruit from across the state of Texas mainly using social media recruitment through platforms such as Facebook and Twitter. With the transition to REDCap Cloud for data management and DocuSign for consenting, this goal was made possible by eliminating the need for in-person appointments. Subject enrolled as cases, those who suffer from low back pain, will continue in the study by completing quarterly surveys either online, by phone, or in-person. Subjects enrolled as controls will only have the one-time survey that is completed after the subject consents. A one-time saliva sample is collected from all cases and controls.

During my internship, I was assigned several daily tasks including monitoring the ORC email for subject questions as well as incoming surveys. After a survey would come in, my duties included insuring it was completed, compensating the subject, and updating any changed contact information. I was also responsible for a group of subjects that preferred to complete

their surveys by phone. Each week, those subjects would be divided between the coordinators to call and complete the surveys, including compensation. If while monitoring the email or interacting with subjects on the phone I was notified that the subject was hospitalized for any reason, I would log this as an adverse event. This information is kept in an on-going excel document to report to the Institutional Review Board once a year, in accordance with the PRECSION protocol.

When recruitment opened back up with our new REDCap Cloud system, part of my tasks including checking DocuSign to see if new consent forms came through. If they did, I would check that they were filled out correctly and countersign the form. From there I would go through the enrollment process by uploading the consent packet to REDCap Cloud, send out the saliva kit, and trigger the saliva kit instructional video to be sent to the subject's email. Once the saliva kit was returned, I would finish enrolling the subject, trigger the baseline survey to be sent, and register the subject in our debit card-based payment system, Greenphire. I would then compensate the subject once the baseline survey was completed. If a subject scheduled an in-person baseline visit, part of my responsibilities was to complete the visit, including the informed consent process. To complete the enrollment process, I would deliver the returned salvia kits to the genetics lab once a week.

One day a week I was also in charge of any consent forms that came through for our new seed grant sub-study, which focused on an informational intervention using the SPADE dimensions. For this study, subjects had to be enrolled in the PRECISION Pain Research Registry. After the subjects consented to enrolling in the sub-study using DocuSign, I was responsible for reviewing and countersigning the document and enrolling the subjects in to either Group 1 (intervention) or Group 2 (control). Group 1 subjects received an email with a graph and interpretation guide highlighting their SPADE scores from their most recent quarterly survey. I

would send out the email and schedule subjects to complete an additional survey one month after they receive the graph. For Group 2, I would send an email out letting them know they would receive their graph one month from that day.

Overall Internship Experience

During my time as an intern, I experienced all different aspects of the research process. Aside from learning the day-to-day operations, I was able to be a part of the meetings and ideas that will advance this research study. This includes discussions of new processes, brainstorming new ideas, and troubleshooting new systems.

When I began as an intern, the ORC was in the middle of a major transition to a new online system, REDCap Cloud. I had the unique opportunity to see how an ongoing study can change and evolve and how that process may be different than starting a new study. With this transition, the ORC staff had to begin new protocols and procedures while trying to balance the 500+ subjects already enrolled in the study. This allowed me as an intern to not only learn these new processes, but observe how to teach the subjects these new processes. Both REDCap Cloud and DocuSign had a learning curve for staff and subjects to fully adjust. Working directly with the subjects was a great experience.

During this transition, the ORC staff also had to look at their previous methods of recruitment. Facebook had been the most effective recruitment method for this project in the past, but when we opened recruitment after the transition to REDCap Cloud, we were not getting the high response that previously obtained. Facebook had changed its algorithms, which forced another set of adjustments in how recruitment was managed. I attended a few social media meetings as well as explore a few marketing ideas on my own. For example, I contacted several cities and school districts about possible advertisement opportunities.

As well as the hands-on experience, I witnessed many different aspects of general research procedures. Submission for continuing review for the ORC team was due May 30, 2019. I observed and assisted with replacing the existing forms with the new updated stamped copies from the IRB. With this major transition to a new system, many parts of existing documents had to be updated even after continuing review. I also assisted in submitting updated IRB packets with updated protocols, consents, surveys, ads, etc.

Budgeting and grant monitoring were other procedures that I was able to observe. Often times, when Cathy had a report to complete, she would have the interns sit in with her to observe how to keep track of all of the different accounts. I also had the opportunity to sit in on a meeting with the Grants department on how to spend grant money according to the grant application.

Not only have I learned how to run certain aspects of this study, by having the opportunity to work with the ORC staff, I have learned so much about the overall research process. I am very grateful that I had the opportunity to work with the ORC staff and see first-hand how research can be so innovative and forward thinking. The experiences that I was able to have while working on the PRECISION Pain Research Registry have allowed me to feel confident as a research coordinator and know that the skills that I have learned here will carry on to any research study that I may work on in the future.

APPENDICES

Appendix A- IRB Approved Forms, Surveys, and Ads

V17 08-14-19

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 and Innovation (PRECISION Pain Research Registry)*

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

Names of each Co-Investigator: *Robert J. Gatchel, PhD, Subhash Aryal, PhD, Nicole Phillips, PhD*

Sponsoring Agency / Company (if applicable): *Osteopathic Heritage Foundation; American Osteopathic Association; University of North Texas Health Science Center*

Sponsor's Grant Number*: OHF – N/A; AOA – 751711713 & 1911751; UNTHSC- N/A*

A. OVERALL REGISTRY SPECIFIC AIMS –

Specific Aim 1: Develop a pain research 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 – Completed December 31, 2018

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.

SUBSTUDY 2 SPECIFIC AIMS – SPADE

Aim 1 – Primary Outcomes: Changes in SPADE Cluster Score and in its Five Component QOL Scale Scores: We hypothesize that subjects allocated to the experimental group will experience significantly better change scores over 1 month on the SPADE cluster and each of its five component Quality of Life (QOL) scales than subjects allocated to the control group, and that the group differences will meet or exceed the threshold for a medium treatment effect size (Cohen's d ≥ 0.5).

Aim 2 – Secondary Outcomes: Changes in Pain Intensity and Back-Specific Functioning: We hypothesize that subjects allocated to the experimental group will experience significantly better change scores over 1 month on a numerical rating scale for pain intensity and on the Roland-Morris Disability Questionnaire relating to back-specific functioning than the control group, and that the group differences will meet or exceed the threshold for a medium treatment effect size (Cohen's d ≥ 0.5).

Aim 3 – Subject Actions Based on QOL Report that Mediate Primary and Secondary Treatment Outcomes at 1 Month: We hypothesize that significant between-group differences in QOL, pain intensity, and back-specific functioning in the trial will be mediated by subject actions prompted by the QOL report provided to those in the experimental group, and that such mediators will persist as significant predictors in statistical analyses that control for moderator variables.

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 research focuses on the prevention and treatment of chronic pain. He holds the Osteopathic Heritage Foundation Distinguished Chair in Clinical Research in honor of Drs. David Richards and Benjamin Cohen, former President and Provost of the University of North Texas Health Science Center. He also directs the Osteopathic Research Center, including its PRECISION Pain Research Registry. The latter studies precision medicine and biopsychosocial approaches to pain management. He received a Midcareer Investigator Award from the National Institutes of Health (NIH), served as an expert panelist for NIH in the area of chronic pain, and completed a four-year term on its National Advisory Council for Complementary and Integrative Health. He directed the OSTEOPATHIC Trial, a five-year study funded by NIH that demonstrated substantial improvements in and recovery from chronic low back pain with osteopathic manipulation. He is presently a Co-Investigator in the $14

million Prevention of Acute to Chronic Back Pain Trial (PACBACK Trial) sponsored by NIH, and recently served on the Work Group that developed NIH's Federal Pain Research Strategy. Internationally, Dr. Licciardone has served as a consultant to the World Health Organization on regulatory and safety issues relating to osteopathy in Europe and other nations. He gave the keynote address at Advancing Osteopathy 2008, a conference celebrating the 10th anniversary of recognition of osteopaths in the United Kingdom's National Health Service, including a preconference reception with the His Royal Highness, The Prince of Wales. Dr. Licciardone is recognized by Expertscape as the leading international authority on osteopathic manipulation.

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 research registry (up to 2,000 cases) will be asked to complete encounters quarterly 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 supplements taken for any conditions, treatments for low back pain, characteristics of physicians who provide low back pain care, and characteristics of pain and pain perception. Biological samples will also be collected to explore genetic and other physical markers of low back pain.

Subjects will be encouraged to complete the consent/enrollment process and all study encounters remotely. Upon request, encounters may be scheduled in-person. Subjects who elect to complete the initial encounter in-person may complete subsequent encounters in-person, by telephone, or online. Please note the initial encounter may not be completed by telephone as it is assumed if subjects are asking for an in-person visit, they would not be comfortable with the process of consenting or returning the saliva sample remotely. Subjects will be recruited throughout the State of Texas using the mechanisms outlined in the recruitment section.

Informed consent and all other enrollment documentation will be executed using an electronic system (such as DocuSign or REDCap). The electronic consent packets will include the informed consent document, the HIPAA authorization, the W-9 form and the web-based payment system FAQ. The packets will be signed and countersigned. Subjects will be required to upload a copy of a valid government identification card that includes a photo and date of birth to confirm age and identity. Each subject will be able to download a copy of the executed consent packet once all parties complete the signing process.

Subjects will provide an email address as part of the enrollment process. If a subject does not have an email address or is not comfortable using the computer, he/she may complete the baseline visit in-person and complete subsequent encounters by telephone. All electronic systems are HIPAA-compliant and password-protected. Only the appropriate key personnel will have access to subjects' personal identifiable information.

For the baseline encounter, 24 months, 48 months and 72 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 side effects related to the medications they take. Subject compensation will be $50 for completion of the baseline, 24-month, 48-month and 72-month surveys.

Subsequent study encounters at 3 months, 6 months, and 9 months will be compensated $25. Compensation for the 12-month, 36-month and 60-month encounters will increase to $30 based on the length of the surveys.

Post-enrollment encounters at 15, 18, 21, 27, 30, 33, 39, 42, 45, 51, 54, 57, 63, 66, and 69 months will be

compensated $10.

Compensation will be provided for each encounter as outlined in the compensation schedule. Subjects will be compensated using a web-based payment system (such as Greenphire). 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. Instructions for using debit card will be provided to each subject.

Because compensation for several milestone encounters have been increased, all active subjects who are not lost to follow-up or those who have not withdrawn, will need to be re-consented (completed summer 2019). Current and future re-consents will be completed electronically. Subjects may also request to re-consent in-person.

For re-consents that are completed in conjunction with a quarterly visit, the subject will receive only the compensation for that scheduled visit. If a subject is asked to re-consent at a time that is not aligned with a quarterly visit, the subject will be compensated $10.

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

A completed IRS W-9 form is required to receive compensation. 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.

Subjects completing the consent process remotely will be mailed a card and cardholder agreement. The card does not have any value until funds are loaded following completion of the encounter.

Study personnel will register the payment card once receipt is confirmed and approve all payments. Confirmation may be confirmed by tracking of packages sent via courier service, by email or by telephone. Subjects will interact with MasterCard customer support to resolve any issues related to the use of the card.

Form A replaces the SA Form and is given at the baseline, 24-month, 48-month, and 72-month encounters. Form B replaces the S3 form and will be used at 3-month, 6-month, and 9-month encounters. Form C will replace the S12 form and is given at 12-month, 36-month and 60-month encounters. Form D will replace the S15 form and will be used at the 15-month, 18-month, 21-month, 27-month, 30-month, 33-month, 39-month, 42-month, 45-month, 51-month, 54-month, 57-month, 63-month, 66-month, and 69-month encounters.

Telephone encounters are available upon request for all but the initial baseline visit as some subjects enrolled in the study are not comfortable using the computer. Study coordinators read to these subjects during in-person and telephone visits and mark the answers in the electronic data capture system on the subjects' behalf. Prospective subjects may screen to determine if they qualify to enroll in the research registry by completing the SQ form electronically, by telephone or in-person. 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 will be told if they are eligible for the study or not, immediately after submitting the screening form. The screening questionnaire requires contact information to be included before the prospective subject is told whether they qualify for the study or not. If a prospective subject chooses not to share contact information, they may close the survey (SQ) without submitting it and no data will be retained. Prospective subjects will be told via instructions included in the online screening tool that their responses to the screening questionnaire will be retained.

If prospective subjects fails the screening, they may opt to be contacted at a later date to reassess eligibility for this research registry or for future research projects. They may also opt out of future contact. Identifiable information (contact information) will be retained for all people who pass or fail the screening for the research registry if they provide that information and submit the screening survey. A script will be used when contacting prospective subjects who passed the screening and request to complete the initial baseline visit in-person.

For those that passed the screening and chose to complete the encounter electronically a series of tasks are required. After subjects view the FAQ video that provides details about the study, subjects will be asked to indicate they are ready to enroll. Other options include, requesting contact with a study coordinator or choosing not to enroll in the study. Once the prospective subject elects to enroll, a link to the consent packet will be displayed for them to click. The consent packet is completed electronically, signed and countersigned. Once the packet is completed, the subject will be able to download a PDF copy. The subject will receive a link to the saliva FAQ video. After the staff receives the completed consent packet, the saliva kit will be mailed to the subject. Once the subject returns the saliva kit to study personnel, the subject will officially be enrolled in the study and the baseline survey link will be sent via email using the automated electronic system. Subjects will be compensated for the baseline visit after all segments of the visit have been completed.

If subject chooses to complete the baseline visit in-person, it will be scheduled as soon as feasible given available appointments, ideally within two to three weeks of the participant passing the screening.

The questions included in study surveys are primarily drawn from the following:

- NIH minimum dataset for chronic low back pain
- PROMIS Quality of Life Measures
- Roland-Morris Disability Questionnaire
- Pain Catastrophizing Scale
- Pain Self-Efficacy Scale Questionnaire
- Items related to diagnosed medical comorbidities
- Communication Behavior Questionnaire
- Consultation and Relational Empathy Measure
- Patient Satisfaction Questionnaire
- Pain Sensitivity Questionnaire
- Comprehensive pharmacological treatments
- Drug Adverse Events
- History of Medical Conditions Inventory
- Use of opioids/NSAIDS for low back pain
- Physician information

Each subject will be asked to complete these questionnaires. The electronic survey requires subjects to answer the questions in one session. The three-hour time frame listed for the initial encounter is the longest it has taken a subject to complete the visit. Most subjects who are comfortable using the computer take less than an hour to complete the survey portion of the encounter. We have left the description of the time for the initial visit at three hours for those subjects who do need that long to complete the encounter. We also recognize that as we move to remote collection of saliva samples, it will take subjects a range of time to complete that task and to take the saliva package to a courier service if pickup is not available in their area. Each subject will be assigned a unique identifying number that will be used to store that person's responses in the electronic data capture system. As PRECISION transitions to the new electronic data capture system paper charts and other paper study documentation will no longer be used and all information will be stored electronically in the secure, HIPPA-compliant, cloud-based space that will host the survey data. These documents and study data

are only accessible by approved key personnel. Once conversion of all documents have been validated, paper charts will be de-identified and destroyed.

For baseline visits completed in person, subjects will be asked to provide a saliva sample for genetic analysis as well as a blood sample. 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. No personal identifiable information will be stored with the blood sample. For subjects completing the baseline visit remotely, PRECISION will not be collecting blood samples because of challenges of processing and shipping the blood samples in a cost-effective manner. The only genetic samples collected from remote subjects will be saliva samples. A kit with specific instructions will be sent to the subject via courier with a prepaid return label included. Subjects will have access to an instructional video that outlines the process for collecting and returning the saliva sample. We anticipate it will take subjects approximately two to three hours to complete the remote baseline encounter once all components are included. Subjects who complete the baseline encounter remotely and in-person will be given the same compensation as the time involved is the same, but is allocated differently based on the tasks required.

All saliva samples will be delivered to the genetics facility in the Center for BioHealth, where they will be stored and analyzed. All genetic samples will be coded with a unique identifying number. Laboratory personnel will not have access to personal identifiable data for any subjects. Genetic samples, biomarker samples and responses to research registry questionnaires will be used for analyses as indicated in the specific aims for the research registry project and for this and future substudies as indicated. Biological samples will also be analyzed in future studies related to low back pain and other conditions related to pain.

Occasionally, study personnel may need to contact research 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 study encounters. 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. Subjects may choose to receive study information using multiple methods of communication.

Inclusion Criteria (Study Population 1, "Cases")

To participate in the research registry, subjects must be:

- 21 years old to 79 years old (documented by an original, valid, government-issued photo identification provided at the baseline encounter)
- Report having low back pain for at least three months; **AND** report having low back pain for at least half of the days for the past six 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 (Study Population 1, "Cases")

To enroll in the research registry, subjects must not be:

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

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

Additional Study Population – (Study Population 2, "Controls")

Data collection for up to 2,000 control subjects (Total for research registry is 4,000 subjects – 2,000 cases and 2,000 controls) will be conducted remotely using the electronic system and the same process as PRECISION subjects. Control subjects may request an in-person visit at the UNT Health Science Center. These control subjects will be recruited using the same venues as subjects with low back pain. They will complete the screening form CON-SQ electronically, by telephone or in-person.

Just as with PRECISION subjects (Population 1), control subjects (Population 2) will complete the appropriate screening questionnaire. Control subjects completing the encounter remotely will provide a saliva sample, and control subjects completing the encounter in-person will provide blood samples in addition to saliva samples as outlined for Population 1. 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). Each control subject will be asked to complete an IRS W-9 form.

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

Inclusion Criteria for (Study Population 2, "Controls")

- 21 years old to 79 years old (documented by an original, valid, government-issued photo identification provided at the baseline encounter)
- Report that pain in any area of their body is experienced less 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, a separate baseline survey, a

separate consent, and separate advertisements (Health Status – Tell Us About Your Health). All documents are marked HEALTH STATUS instead of PRECISION. 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 (Population 1).

Substudy 2: SPADE (New Substudy)

Subjects for substudy 2 will be selected from PRECISION Pain Research Registry participants based on their responses to specific questions and their scores on specific questionnaires at a quarterly visit that occurs at either the baseline, 3-month, 6-month or 9-month encounter. This study focuses on various Quality of Life (QOL) measures including sleep disturbance, pain interference with activities, anxiety, depression, and low energy/fatigue (SPADE). Subjects must have a SPADE cluster score ≥55 to be eligible for this study and must be categorized as having chronic low back pain based on their survey responses at their most recent quarterly encounter. A separate consent form (SPADE substudy Consent) will be completed by each subject within approximately two weeks of the quarterly visit where he/she were determined to be eligible for the substudy. Subjects participating in this substudy will be randomly assigned to an experimental or control group.

Approximately 146 subjects (73 in the experimental group and 73 in the control group) will be recruited to this substudy. Each subject in the experimental group will receive a graph of the individual components of the SPADE score that may be shared with his or her physician. They will also receive an interpretation guide. One month later, the subjects randomized to the experimental group will complete a survey to evaluate how the information in the graph may have improved his or her qualify of life. Subjects will also respond to questions related to several outcome measures that are typically included in the quarterly surveys such as the numerical pain rating scale, the Roland-Morris Disability Questionnaire and the PROMIS-29. Subjects in the experimental group will be compensated $25 for the first substudy encounter where consent is signed and the graph is provided with instructions for use. One month later, they will be paid $10 compensation for completing the additional short survey that will take approximately 10-30 minutes. Subjects who consent to participating in this study that are randomized to the control group will receive $25 when they sign the consent document, but will not receive the graph of their SPADE score or the interpretation guide. Instead, they will be given the graph and guide in one month, at which time, they will receive $10. Subjects randomized to the control arm of this substudy will not complete the additional survey. Subjects will be invited to participate in the substudy if they are completing their baseline, 3-month, 6-month or 9-month encounter as these are the only encounters that offer the opportunity to complete surveys that provide the requisite outcomes data.

We anticipate that this substudy with the one-month follow-up will conclude by October 31, 2019, depending on the pace of recruitment. Please note the timeline for follow-up has been changed because of the delay in transitioning to REDCap Cloud that was rooted in programming issues.

Inclusion Criteria (Substudy 2)

To participate in this substudy, subjects must:

- Be categorized as having chronic low back pain
- Have a SPADE cluster score of ≥ 55

Exclusion Criteria (Substudy 2)

To participate in this substudy, subjects must not:

- Be categorized as having subacute low back pain
- Have a SPADE cluster score < 55

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 the cloud-based electronic data capture and study management system will be periodically downloaded into a database such as SPSS or SAS for statistical analysis. Since each subject will be assigned a unique identifying number, research data will be stored by each subject's unique identifying number in a secure, password-protected, HIPAA-compliant electronic system that is only accessible by approved key personnel. All data previously downloaded from Qualtrics will be kept on computer hard drives, external hard drives, or secure servers in password-protected areas.

The PI and the research assistant director will have administrator access to the research management and electronic data capture system. They will define roles for other users and will restrict write access based on each staff member's job duties. Only key personnel will have access to the system. The system provides a date/time stamp as well as identifies which user made modifications. Permission to modify data will be very limited and on an as needed basis only. An example of data that may need to be modified includes updating a subject's contact information or correcting the spelling of a drug name in the list of medications that each subject completes at various time points.

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 research 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 in other parts of the protocol and will be 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 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 research registry, we have obtained 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:

PRECISION Pain Research Registry will be using an electronic data capture and study management system for all subjects, whether they are new or currently active subjects. Subjects will be encouraged to complete all encounters, including the consent process and the baseline encounter remotely. Subjects who are not comfortable using a computer or who do not have access to a computer may request an in-person visit to complete the consent process and baseline encounter. In this case, all

remaining study visits would be conducted by phone unless the subject specifically requests to complete subsequent encounters in-person. In-person visits are conducted at the UNT Health Science Center. Subjects who initially consent in-person may also re-consent in-person. In-person or phone encounters or re-consents may be converted to online encounters at any time by notifying study personnel.

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 3130*xl* and/or 3500*xl* 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 Sequencher™ 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 research 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 a valid photo id; complete baseline survey (Form A); provide biological samples for genetics and biomarker analysis; obtain information about medications and supplements. This encounter (including informed consent) may be completed remotely or in-person. Subjects completing the visit remotely will provide saliva samples while subjects completing the encounter in-person will also provide blood samples.	Up to 3 hours	$50
Months 3, 6 and 9	Update contact information; complete survey (Form B); obtain information about medications and supplements. Encounter may be completed electronically, by telephone or in-person.	30 minutes to 1 hour	$25
Months 12, 36, and 60	Update contact information; complete survey (Form C); obtain information about medications and supplements. Encounter may be completed electronically, by telephone or in-person.	30 minutes to 1 hour	$30
Months 15, 18, 21, 27, 30, 33, 39, 42, 45, 51, 54, 57, 63, 66 and 69	Update contact information; complete survey (Form D). Encounters may be completed electronically, by telephone or in-person.	15-20 minutes	$10
Months 24,48, and 72	Update contact information; complete survey (Form A). Encounters may be completed electronically, by telephone or in-person.	45 minutes to 1 hour	$50

Estimated Period of Time to Complete the SubStudy (Substudy 2):

Encounter	Tasks	Estimated Time to Complete	Compensation
Primary (Enroll)	Execute informed consent. Complete primary REDCap survey (SPADE Form); Subjects randomized to the experimental group will be provided with a SPADE score graph and an interpretation guide. Subjects randomized to the control arm will not receive the graph/guide at this encounter.	10-20 minutes	$25
Secondary (Exit)	Subjects that were randomized to the experimental arm of the substudy will complete the SPADE survey. Subjects randomized to the control group will not complete the SPADE survey but will receive the SPADE score graph and an interpretation guide.	10-30 minutes	$10

F. HUMAN SUBJECTS –

*1) **Description of Subjects**:*

We intend to recruit up to 4,000 subjects (2,000 subjects with low back pain and 2,000 control subjects) for this research 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. We plan to recruit participants from across the State of Texas using predominantly social media and internet-based platforms, but we will also use more traditional methods such as those outlined here for local recruitment.

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

We aim to recruit a racially and ethnically diverse group of subjects that generally follows the demographics reported for the State of Texas 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 4,000 subjects (2,000 subjects with low back pain and 2,000 control subjects) will be enrolled in the initial phase of this research registry.

3) ***Describe both Inclusion / Exclusion Criteria:***

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

To participate in the research registry, subjects must be:

- 21 years old to 79 years old (documented by an original, valid, government-issued photo identification provided at the baseline encounter)
- Report having low back pain for at least three months; **AND** report having low back pain for at least half of the days in the past six 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 Subjects with Low Back Pain (Study Population 1)

To enroll in the research registry, subjects must not be:

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

Inclusion Criteria for Control Subjects (Study Population 2):

- 21-years-old to 79-years-old (documented by an original, valid, government issued photo identification provides at baseline encounter)
- Report that pain in any area of their body is experienced less 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 research 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 research registry. People over 79- years old 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 subjects 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)	508
American Indian / Native American	40
Asian	200
Caucasian (White)	3168
Native Hawaiian / Pacific Islander	4
Other /Unknown	80
Ethnicity	**Targeted Enrollment**
Hispanic/Latino	1576
Not Hispanic/Latino	2424
Gender	**Targeted Enrollment**
Female	2012
Male	1988

The age range of participants for this research 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 research registry.

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

We intend to recruit up to 4,000 subjects (2,000 subjects with low back pain and 2,000 control subjects) using 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. We plan to recruit participants from across the State of Texas using predominantly social media and internet-based platforms, but we will also use traditional methods such as those outlined here for local recruitment.

In addition to posting flyers in the waiting area of local clinics (DFW Metroplex), 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 research registry from physicians throughout the DFW Metroplex and across the State of Texas 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.

G. RISK/BENEFIT ANALYSIS –

1) Level of Risk / Description of Benefit:

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

2) Describe How the Anticipated Benefit Justifies the Risk:

The risk to participants in this research registry is a minor increase over minimal risk. There is no direct benefit to participants in research 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 in the main research registry, however, Substudy 2 does include an intervention that entails providing subjects randomized to the experimental arm of the study with a graph of specific quality of life measure that may be shared with their health care provider. Future benefits of the research registry and any substudies 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 research 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 have obtained a Certificate of Confidentiality to prevent us from being required to disclose such genetic data to outside agencies or parties once such data it 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; 3-, 6- and 9-month 9 encounters - $25; 12-, 36-, and 60-month encounters - $30; 24-, 48-, and 72-month encounters - $50; and 15-, 18-, 21-, 27-, 30-, 33-, 39-, 42-, 45-, 51-, 54-, 57-, 63-, 66-, and 69-month encounters - $10. Compensation is based on survey length for each encounter, and will be made via a secure, web-based payment system.

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

Subjects completing Substudy 2 will receive $25 compensation at the initial encounter and $10 compensation at the second encounter.

I. SUBJECT COSTS –

The only anticipated costs to subjects for this pain research registry is the transportation cost if a subject chooses to visit the UNTHSC campus to complete any of the study visits. The cost is minimal, and subjects will receive compensation sufficient to cover any travel expenses incurred. Subjects completing the study remotely may incur costs if they need to deliver samples remotely to the courier service for return to the study team instead of being able to contact the courier service for a pickup. Finally, if subjects choose to receive payment confirmation messages via text, they may incur costs for the text messages based on the parameters of their cell phone service plan.

J. Historical Protocol Modifications

- Substudy 1 for subjects 1-51 only: Data collected for the substudy includes asking subjects several questions related to their relationship with the physician who treated them for their low back pain. Questions focused 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. The same information was collected for subjects 1-51. A separate consent (AOA Substudy Consent) was completed by each subject. The subject would then be asked to complete the online survey (Form AOA1) in addition to the survey for that visit. Subjects did not receive any additional compensation for completing this survey.

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

- The research registry will no longer manage subjects using paper documentation, this will include paper consent, HIPAA, IRS W9 along with enrolling by U.S. Postal Service, and completing survey by paper.

- Initial study payments were provided via Walmart physical or e-gift cards, all payments have been transitioned to a web-based payment system.

- If potential subject did not provide required documents at the baseline visit, a one-time payment of $10 would be given to avoid undue hardship in covering time and travel cost. This has been eliminated as most subjects will consent and enroll remotely. Subjects choosing to complete the baseline visits in-person will be instructed to bring the appropriate documents and information prior to the visit. Historically, we have only used this payment structure a few times each year, so we do not feel that eliminating the payment option creates a hardship for subjects.

K. 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
Nicole Phillips, PhD, Microbiology, Immunology and Genetics

Other Key Personnel:
Cathleen Kearns, BA, Project Manager
Shweta Bhatnagar, Clinical Research Fellow
Patrick Bibb, Clinical Research Fellow
Maryam Burney, Clinical Research Fellow
Savannah Cooper, Student Research Assistant/Project Coordinator
Courtney Hall, Laboratory Technician
Zachary Noah Hendrix, Clinical Research Management Intern/Project Coordinator
Samantha Johnson, BS, Project Coordinator
Annie Lin, Clinical Research Fellow
Jonathan Lopez, Clinical Research Fellow
Fatma Ozguc, Clinical Research Fellow
Vishruti Pandya, Student Research Assistant/Project Coordinator
Jake Powell, Clinical Research Fellow
Theodore Price, PhD, Laboratory Collaborator – UT Dallas
Pradipta Ray, PhD, Laboratory Collaborator – UT Dallas
Benjamin Romanowski, Clinical Research Fellow
Justin Salman, Clinical Research Fellow
Monika Schmitt, Clinical Research Fellow
Matthew Schultz, Clinical Research Fellow
Talisa Silzer, Laboratory Technician
Briana Smith, Laboratory Technician
Varsha Sridhar, Clinical Research Fellow
Jie Sun, Laboratory Technician
Diana Tavarres Ferreira, PhD, Laboratory Collaborator – UT Dallas

Apollo Tran, Clinical Research Fellow
Annesha White, PharmD, MS, PhD, Pharmacogenetics Consultant
Austin Wolstein, Research Student Fellow

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

TITLE:	Pain Registry for Epidemiological, Clinical, and Interventional Studies and Innovation (PRECISION Pain Research Registry)
PRINCIPAL INVESTIGATOR:	John C. Licciardone, DO, MS, MBA
INSTITUTION:	University of North Texas Health Science Center

NAME: _____

IMPORTANT INFORMATION BEFORE YOU JOIN THIS STUDY

You are being invited to participate in a research registry. 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 or call study personnel at 817-735-5410. You may also reach study personnel by email at ORCstudyoperations@unthsc.edu. Once the form is signed, you may download a PDF copy of it and other documents used in the consent process for your records. If you complete the consent process in-person, you will receive a printed copy of the consent form for your records.

SUMMARY

- There are no treatments or diagnoses provided in this research registry. We will ask you to answer questions that tell us about your experience with low back pain and how it affects your life, both physically and emotionally as well as about various treatments you may have used for your low back pain.
- 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 research registry. We will pay you for your time to participate in the research registry. The first encounter may be completed electronically (remotely) or in-person at the University of North Texas Health Science Center campus in the cultural district in Fort Worth.
- If you are completing the encounter electronically, we will ask you to provide a saliva sample that you will mail back to us. Specific instructions and a prepaid airbill will be provided. If you choose to complete the visit in-person, we will ask you to provide both a saliva and blood sample. The biological samples will be used for genetic and biomarker analysis.
- You will be asked to provide a valid, government-issued identification that includes your photo and birthdate to complete the encounter. If you do not provide the identification, you will not be

enrolled in the study. If you are completing this consent process electronically, you will be asked to upload a photo or copy of your identification card at the end of the consent document.

- You will also be asked to sign a HIPPA authorization form that provides more information about your privacy.
- You will be asked to complete an IRS W-9 form because compensation you receive for participating in the research 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 research registry, but we will not be able to compensate you.
- You will be asked to provide 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 input 'NONE' within the survey collection.
- You will be asked to complete quarterly encounters for an indefinite period of time. These encounters may be completed electronically, by telephone or in-person. Please note that you will need to provide a valid email address in order to complete subsequent encounters electronically.
- You will be compensated for each encounter you complete. Please note that we do not give compensation in cash.
- Members of the research team will have access to the information you provide through the surveys you complete and to your biological data. All information will be stored by a unique number assigned to you.
- Only a few members of the research team who conduct and oversee the visit will have access to information that identifies you or links you to your data by name. Your responses to surveys and personal identifiable information is stored on a HIPPA-compliant, password-protected server.
- Research registries continue for an unspecified amount of time. Based on your participation in this research 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 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. We use your saliva (and blood samples if you are completing the encounter in-person) to identify underlying genetic traits that may be associated with specific low back pain in order to improve future treatments. All genetic analysis is used for research purposes only. We do not sell your information, nor do we share it with you or your physician. Finally, we will ask you about the medications and supplements you take for any condition and treatments you receive for your low back pain.

WHAT YOU WILL DO DURING THE STUDY

This is a research registry focused on low back pain. In this research 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 research registry is to collect information that helps us better understand the natural history of low back pain and how it is treated. We intend to recruit approximately 4,000 subjects for this research registry.

Once you complete and sign this consent document, the HIPAA Authorization form, an IRS W-9 form, and provide or upload a copy of an original, valid, government-issued identification that includes your photo and birthdate, you will be asked to provide a saliva sample for genetic and biomarker analysis. If you are completing the encounter electronically, a saliva kit will be mailed to you with specific instructions for collecting the sample and returning it to us. We will provide a prepaid airbill for you to return the sample to us. In the packet with the saliva kit, we will also include the debit MasterCard that we use to compensate you for your participation.

If you do not provide 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 research registry, but we will not be able to compensate you.

If you are completing the consent process and the encounter in-person, the coordinator will provide specific instructions to you throughout the visit. You will also be asked to provide a blood sample (three tubes - approximately 2 tablespoons) that will be drawn by certified personnel.

Part of the blood sample will also be stored for future tests. Saliva (and blood samples if completing the visit in-person) will be used to look at DNA, biomarkers, and other substances that may be related to low back pain. Please note that these samples are analyzed for research purposes only and are not shared with you or your healthcare provider.

We will 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 electronically. If you are completing the visit in-person, the research coordinator will be available to assist you with any questions or problems completing the survey. The questionnaire must be completed in one session. If you are completing the survey remotely and have questions, please call the research coordinator at 817-735-5410. You may also reach study personnel by email at ORCstudyoperations@unthsc.edu.

Your name, any personal information that may identify you, or your contact information will not be stored with your saliva or blood sample (if applicable).

The genetic (saliva) sample and the blood sample (if applicable) that 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 encounter, although most people the encounter in a much shorter time. We will compensate you $50 for completing this encounter. (Compensation will not be given in cash)

You will be asked to complete subsequent 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. These encounters may be completed electronically, by telephone

or in-person. Please note that you will need to provide a valid email address in order to complete follow-up encounters electronically. 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 9 months after you enroll in the study. (Compensation will not be given in cash)

Quarterly follow-up encounters at 12, 36, and 60 months will take approximately 30 minutes to an hour; compensation for these encounters will be $30. Encounters at 24-months, 48-months and 72-months after you enroll in the study will take approximately 45 minutes to one hour to complete and you will receive compensation of $50. Encounters at 15, 18, 21, 27, 30, 33, 39, 42, 45, 51, 54, 57, 63, 66 and 69 months after you enroll in the study will take approximately 15-20 minutes to complete. You will receive compensation of $10 for each of these encounters. Encounters may be completed electronically, by telephone 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. 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. We have obtained 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 Confidentiality to understand more about how this Certificate may help protect information you provide to us during this study.

Blood Draw (In-person visit only)

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 study personnel, at 817-735-5410. You may send questions about your participation in the study to orcstudyoperations@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 research 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 research 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 on a HIPAA-compliant, password-protected server.

Because we are collecting genetic information in this research registry, we have obtained a Certificate of Confidentiality, issued by the National Institutes of Health. This Certificate allows 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.

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 (if applicable) 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 visit at the UNT Health Science Center if you choose that option, or the travel cost to take your saliva kit to a courier location. 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 encounters 3, 6, and 9 months. Compensation for the 12-, 36-, and 60-month encounters will be $30. Compensation for encounters at 24-, 48- and 72-months will be $50, and compensation for encounters at 15-, 18-, 21-, 27-, 30-, 33-, 39-, 42-, 45-, 51-, 54-, 57-, 63-, 66-, and 69- months post-enrollment will be $10 each. Compensation is based on survey length, and will be made within two business days after completing the encounter electronically or by phone. Compensation for in-person visits will be made at the end of the visit. (Compensation will not be given in cash).

If you are asked to re-consent at a time that is not aligned with your quarterly encounter, you will be compensated an additional $10 (Compensation will not be given in cash).

You will receive specific information and instructions about the payment process.

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 income from the UNT Health Science Center that, combined with compensation from this study, exceeds $600.

LEAVING THE STUDY

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

You also have the right to stop participating in the research 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 (if applicable) unless you send us a written request asking us to discard these items.

Any such request must be made by email to the Study Investigator at ORCstudyoperations@unthsc.edu. If you do not have access to email and wish to submit this request, please call study personnel at 817-735-5410 for specific instructions.

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 may download a copy of this signed agreement. If you complete the consent process in-person, you will receive a printed copy of the consent form for your records.

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 research registry.

I have been told that to participate in this research registry, I need to give a saliva sample for genetic analysis, and a blood sample (if completing the consent process and initial visit in-person) for DNA and biomarker analysis. I agree to allow my saliva and blood samples (if applicable) to be used for this project and for future projects. I understand that my saliva and blood (if applicable) 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

If you are consenting remotely, please upload an image of your valid government-issued identification that includes your photo and birthdate using the tag below. You may take a photo of your identification and upload it from your device. You also may scan your identification and upload as a PDF, JPEG or PNG file.

Form A - Baseline, 24 months, 48 months and 72 months (IRB Note Only)

NIH Minimum Dataset

INFORMATION ABOUT YOU AND YOUR LOW BACK PAIN

INFORMATION ABOUT YOU

INTRODUCTION

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.

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.

.

INTRODUCTION

Thank you for participating in our survey. Your responses are very important to us. The survey questions ask you about various aspects of your health status, including medications and treatments that you have received. You must complete an entire section before proceeding to the next section.

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

Today's date:

(YYYY-MM-DD)

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

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

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.)

- ◯ 0
- ◯ 1
- ◯ 2
- ◯ 3
- ◯ 4
- ◯ 5
- ◯ 6
- ◯ 7
- ◯ 8
- ◯ 9
- ◯ 10

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

- ◯ Yes
- ◯ No
- ◯ Not sure

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

Stomach pain?

- ◯ Not at all
- ◯ A little bit
- ◯ A lot

Pain in your arms, legs, or joints other than your spine or back?

- ◯ Not at all
- ◯ A little bit
- ◯ A lot

Headaches?

- ◯ Not at all
- ◯ A little bit
- ◯ A lot

Widespread pain or pain in most of your body?

- ◯ Not at all
- ◯ A little bit
- ◯ A lot

Have you ever had a low back operation?

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

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

Have you even been unemployed or unable to do your usual work for 1 month or longer?

- ◯ Yes
- ◯ No

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

Have you ever received disability or workers' compensation benefits because you were unable to work?

- ◯ 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 worker's compensation benefits

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

- ◯ Yes
- ◯ No

What is your age? _____

What is your gender?

- ◯ Male
- ◯ Female

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

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

- ◯ Hispanic or Latino
- ◯ Not Hispanic or Latino

What is your educational 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
- ◯ Master's degree
- ◯ Professional school degree (e.g., physician, dentist, attorney)
- ◯ Doctoral degree (e.g., Ph.D)

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

How would you describe your cigarette smoking?

- ◯ Never smoked
- ◯ Current Smoker
- ◯ Used to smoke, but have now quit

What is your height?

- 4'7"
- 4'8"
- 4'9"
- 4'10"
- 4'11"
- 5'
- 5'1"
- 5'2"
- 5'3"
- 5'4"
- 5'5"
- 5'6"
- 5'7"
- 5'8"
- 5'9"
- 5'10"
- 5'11"
- 6'
- 6'1"
- 6'2"
- 6'3"
- 6'4"
- 6'5"
- 6'6"
- 6'7"
- 6'8"
- 6'9"
- 6'10"
- 6'11"

What is your weight in pounds?

Subject's BMI

CONTACT INFORMATION

Your current contact information:
Phone number: [subject_phone]Mailing address:
[street_address] [city], [state]
[zipcode]

Note: Contact Information pulls from subject profile

Has your contact information changed?

- ◯ Yes
- ◯ No

What is your new contact information?

LEGEND

Cases

Controls

Research Team Only

These questions are only included in the baseline survey for cases and controls.

Please note that last question about new contact information only displays if the subject indicates their contact information has changed.

PROMIS-29

HOW LOW BACK PAIN AFFECTS YOUR LIFE

YOUR QUALITY OF LIFE

Q1. Please answer the following 4 questions.

Are you able to do chores such as vacuuming or yard work?

- ◯ Without any difficulty
- ◯ With a little difficulty
- ◯ With some difficulty
- ◯ With much difficulty
- ◯ Unable to do

Are you able to go up and down stairs at a normal pace?

- ◯ Without any difficulty
- ◯ With a little difficulty
- ◯ With some difficulty
- ◯ With much difficulty
- ◯ Unable to do

Are you able to go for a walk of at least 15 mins?

- ◯ Without any difficulty
- ◯ With a little difficulty
- ◯ With some difficulty
- ◯ With much difficulty
- ◯ Unable to do

Are you able to run errands and shop?

- ◯ Without any difficulty
- ◯ With a little difficulty
- ◯ With some difficulty
- ◯ With much difficulty
- ◯ Unable to do

PHYSICAL FUNCTION RAW SCORE: _____

PHYSICAL FUNCTION SCORE _____

Q2. Please respond to the following 4 statements. In the past 7 days...

I have felt fearful.

- ◯ Never
- ◯ Rarely
- ◯ Sometimes
- ◯ Often
- ◯ Always

I found it hard to focus on anything other than my anxiety.

- ◯ Never
- ◯ Rarely
- ◯ Sometimes
- ◯ Often
- ◯ Always

My worries overwhelmed me.

- ◯ Never
- ◯ Rarely
- ◯ Sometimes
- ◯ Often
- ◯ Always

I felt uneasy.

- ◯ Never
- ◯ Rarely
- ◯ Sometimes
- ◯ Often
- ◯ Always

ANXIETY RAW SCORE _____

ANXIETY SCORE _____

Q3. Please respond to the following 4 statements. In the past 7 days...

I felt worthless.

- ◯ Never
- ◯ Rarely
- ◯ Sometimes
- ◯ Often
- ◯ Always

I felt helpless.

- ◯ Never
- ◯ Rarely
- ◯ Sometimes
- ◯ Often
- ◯ Always

I felt depressed.

- ◯ Never
- ◯ Rarely
- ◯ Sometimes
- ◯ Often
- ◯ Always

I felt hopeless.

- ◯ Never
- ◯ Rarely
- ◯ Sometimes
- ◯ Often
- ◯ Always

DEPRESSION RAW SCORE _____

DEPRESSION SCORE _____

Q4. Please respond to the following 4 statements or questions. During the past 7 days...

I felt fatigued.

- ◯ Not at all
- ◯ A little bit
- ◯ Somewhat
- ◯ Quite a bit
- ◯ Very much

I have had trouble starting things because I am tired.

- ◯ Not at all
- ◯ A little bit
- ◯ Somewhat
- ◯ Quite a bit
- ◯ Very much

How run-down did you feel on average?

- ◯ Not at all
- ◯ A little bit
- ◯ Somewhat
- ◯ Quite a bit
- ◯ Very much

How fatigued were you on average?

- ◯ Not at all
- ◯ A little bit
- ◯ Somewhat
- ◯ Quite a bit
- ◯ Very much

FATIGUE RAW SCORE _____

FATIGUE SCORE _____

Q5. In the past 7 days...

My sleep quality was...

- ◯ Very poor
- ◯ Poor
- ◯ Fair
- ◯ Good
- ◯ Very good

Q6. Please respond to the following 3 statements. In the past 7 days...

My sleep was refreshing.

- ◯ Not at all
- ◯ A little bit
- ◯ Somewhat
- ◯ Quite a bit
- ◯ Very much

I had a problem with my sleep.

- ◯ Not at all
- ◯ A little bit
- ◯ Somewhat
- ◯ Quite a bit
- ◯ Very much

I had difficulty falling asleep.

- ◯ Not at all
- ◯ A little bit
- ◯ Somewhat
- ◯ Quite a bit
- ◯ Very much

SLEEP DISTURBANCE RAW SCORE _____

SLEEP DISTURBANCE SCORE _____

Q7. Please respond to the following 4 statements.

I have trouble doing all of my regular leisure activities with others.

- ◯ Never
- ◯ Rarely
- ◯ Sometimes
- ◯ Usually
- ◯ Always

I have trouble doing all of the family activities that I want to do.

- ◯ Never
- ◯ Rarely
- ◯ Sometimes
- ◯ Usually
- ◯ Always

I have trouble doing all of my usual work (include work at home).

- ◯ Never
- ◯ Rarely
- ◯ Sometimes
- ◯ Usually
- ◯ Always

I have trouble doing all of the activities with friends that I want to do.

- ◯ Never
- ◯ Rarely
- ◯ Sometimes
- ◯ Usually
- ◯ Always

PARTICIPATION IN SOCIAL ROLES RAW SCORE _____

PARTICIPANT IN SOCIAL ROLES SCORE _____

Q8. Please answer the following 4 questions. In the past 7 days...

How much did pain interfere with your day-to-day activities?

- ◯ Not at all
- ◯ A little bit
- ◯ Somewhat
- ◯ Quite a bit
- ◯ Very much

How much did pain interfere with work around the home?

- ◯ Not at all
- ◯ A little bit
- ◯ Somewhat
- ◯ Quite a bit
- ◯ Very much

How much did pain interfere with your ability to participate in social activities?

- ◯ Not at all
- ◯ A little bit
- ◯ Somewhat
- ◯ Quite a bit
- ◯ Very much

How much did pain interfere with your household chores?

- ◯ Not at all
- ◯ A little bit
- ◯ Somewhat
- ◯ Quite a bit
- ◯ Very much

PAIN INTERFERENCE RAW SCORE _____

PAIN INTERFERENCE SCORE _____

SPADE SCORE _____

LEGEND

Cases

Controls

Research Team Only

Do You Have Low Back Pain?

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

To enroll in the PRECISION Pain Research Registry, you will be asked to answer questions approximately every three months. If you qualify to participate, all encounters may be completed electronically. You may also complete the initial encounter in-person at the University of North Texas Health Science Center campus in Fort Worth's Cultural District. If you complete the inital encounter in-person, you may complete future encounters by telephone, in-person or online.

All participants will be asked to provide a one-time saliva sample for analysis of DNA and other biomarkers. If you choose to complete the initial visit in-person, you will also be asked to provide a blood sample for biomarker analysis.

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 email us at orcstudyoperations@unthsc.edu or call 817-735-5410. You may also **click here** to complete a screening form to determine if you qualify for the registry. We look forward to hearing from you.

IRB APPROVED • JULY 9, 2019 • NORTH TEXAS REGIONAL IRB • UNT HEALTH SCIENCE CENTER

NORTH TEXAS REGIONAL IRB

Approval Date: August 16, 2019

UNT HEALTH SCIENCE CENTER
PRECISION PAIN RESEARCH REGISTRY
Where Science Meets Practice

Do You Have Low Back Pain?

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

Essentials of the PRECISION Pain Research Registry:

- 100% remote encounters available
- Ongoing quarterly encounters
- Participants provide one-time saliva sample for DNA analysis
- Participants must be 21- to 79-years-old and may not be pregnant
- Compensation for each encounter completed

Visit https://bit.ly/2HbBlzl to see if you qualify

You may also Email orcstudyoperations@unthsc.edu
or call 817-735-5410

IRB APPROVED • SEPTEMBER 10, 2019
NORTH TEXAS REGIONAL IRB • UNT HEALTH SCIENCE CENTER

UNT HEALTH SCIENCE CENTER
PRECISION PAIN RESEARCH REGISTRY
Where Science Meets Practice


Low Back Pain
Research Study
Help us learn more about low back pain. See if you qualify to be a paid research participant in Texas.


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Help us learn more about low back pain. See if you qualify to be a paid research participant in Texas.

APPENDIX B- Internship Logs

Internship Log

6/3/19

- Research Fellowship Class with Dr. Licciardone
- Learned new re-consent process with DocuSign and set in on in person consent
- Reviewed process for creating Greenphire end of month report with Cathy
- Verified Visit dates for subjects upcoming visits and noted their Missed Visit date

6/4/19

- Research Fellowship Class with Dr. Licciardone
- Meeting with Dr. Dory to discuss research project
- Re-consented 2 subjects in person; including signing and compensating subject for coming in
- Updated charts from data clean-up for migration to REDCAP cloud

6/5/19

- Updated charts from data clean-up for migration to REDCAP cloud
- Re-consented 5 subject in person; including signing and compensating
- Meeting with Cathy over Research project
- Monitored Doc-U-Sign and completed multiple online re-consents; including signing and compensating

6/6/19

- Updated charts from data clean-up for migration to REDCAP cloud
- Created Excel record will all of the charts that were updated
- Monitored Doc-U-sign and completed multiple online re-consents; including signing and compensating
- Re-consented 2 subjects in person; including signing and compensating
- Discussion with Cathy the ramifications of changing procedures, requirements, or data collection processes during a longitudinal study

6/7/19

- Monitored Doc-U-sign and completed multiple online re-consents; including signing and compensating
- Monitored ORC e-mail and responded to questions about Doc-u-Sign and the REDCap Cloud Transition
- Re-consented 5 subjects in person; including signing and compensating
- Contacted subjects to schedule re-consent (In person or needing to re-send the electronic version)
- Verified Visit dates for subjects upcoming visits and noted their missed visit date

6-7-19

Internship Log

6/10/19

- Research Fellowship Class with Dr. Licciardone
    - Included presentation over searching for scientific literature
- Monitored DocuSign and completed multiple online re-consents; including signing and compensating
- Monitored ORC e-mail and responded to questions about DocuSign and the REDCap Cloud Transition
- Staff meeting with the ORC research staff

6/11/19

- Monitored DocuSign and completed multiple online re-consents; including signing and compensating
- Contacted subjects that have not completed new consent and re-sent consent documents
- Re-consented 2 subjects in person; including signing and compensating subject for coming in
- 1st committee meeting to discuss research topic

6/12/19

- Monitored DocuSign and completed multiple online re-consents; including signing and compensating
- Learned out the process of closing out a study
    - Filling out close-out form
    - De-identifying information
- Learned out to upload and send out a new document in DocuSign
- Worked on Research Proposal

6/13/19

- Monitored DocuSign and completed multiple online re-consents; including signing and compensating
- Answered phone calls and emails from subjects over DocuSign and the REDCap Cloud transition
- Worked on CRM Research Proposal
- Started Revised Common Rule CITI Training

6/14/19

1. Monitored Docu sign and completed multiple online re-consents; including signing and compensating
2. Monitored ORC e-mail and responded to questions about DocuSign and the REDCap Cloud Transition
3. Finished Revised Common Rule CITI Training
4. CRM Research Proposal revisions with Cathy
5. Updated Continuing Review IRB amendments document
6. Created Document of subjects with visits in April and May to be prepared when surveys open

Internship Log

6/3/19

- Research Fellowship Class with Dr. Licciardone
- Learned new re-consent process with DocuSign and set in on in person consent
- Reviewed process for creating Greenphire end of month report with Cathy
- Verified Visit dates for subjects upcoming visits and noted their Missed Visit date

6/4/19

- Research Fellowship Class with Dr. Licciardone
- Meeting with Dr. Dory to discuss research project
- Re-consented 2 subjects in person; including signing and compensating subject for coming in
- Updated charts from data clean-up for migration to REDCAP cloud

6/5/19

- Updated charts from data clean-up for migration to REDCAP cloud
- Re-consented 5 subject in person; including signing and compensating
- Meeting with Cathy over Research project
- Monitored Doc-U-Sign and completed multiple online re-consents; including signing and compensating

6/6/19

- Updated charts from data clean-up for migration to REDCAP cloud
- Created Excel record will all of the charts that were updated
- Monitored Doc-U-sign and completed multiple online re-consents; including signing and compensating
- Re-consented 2 subjects in person; including signing and compensating
- Discussion with Cathy the ramifications of changing procedures, requirements, or data collection processes during a longitudinal study

6/7/19

- Monitored Doc-U-sign and completed multiple online re-consents; including signing and compensating
- Monitored ORC e-mail and responded to questions about Doc-u-Sign and the REDCap Cloud Transition
- Re-consented 5 subjects in person; including signing and compensating
- Contacted subjects to schedule re-consent (In person or needing to re-send the electronic version)
- Verified Visit dates for subjects upcoming visits and noted their missed visit date

6-7-19

Internship Log

6/10/19

- Research Fellowship Class with Dr. Licciardone
    - Included presentation over searching for scientific literature
- Monitored DocuSign and completed multiple online re-consents; including signing and compensating
- Monitored ORC e-mail and responded to questions about DocuSign and the REDCap Cloud Transition
- Staff meeting with the ORC research staff

6/11/19

- Monitored DocuSign and completed multiple online re-consents; including signing and compensating
- Contacted subjects that have not completed new consent and re-sent consent documents
- Re-consented 2 subjects in person; including signing and compensating subject for coming in
- 1st committee meeting to discuss research topic

6/12/19

- Monitored DocuSign and completed multiple online re-consents; including signing and compensating
- Learned out the process of closing out a study
    - Filling out close-out form
    - De-identifying information
- Learned out to upload and send out a new document in DocuSign
- Worked on Research Proposal

6/13/19

- Monitored DocuSign and completed multiple online re-consents; including signing and compensating
- Answered phone calls and emails from subjects over DocuSign and the REDCap Cloud transition
- Worked on CRM Research Proposal
- Started Revised Common Rule CITI Training

6/14/19

1. Monitored Docu sign and completed multiple online re-consents; including signing and compensating
2. Monitored ORC e-mail and responded to questions about DocuSign and the REDCap Cloud Transition
3. Finished Revised Common Rule CITI Training
4. CRM Research Proposal revisions with Cathy
5. Updated Continuing Review IRB amendments document
6. Created Document of subjects with visits in April and May to be prepared when surveys open

6-17-19

Internship Log

6/17/19

- Monitored DocuSign and completed multiple online re-consents; including signing and compensating
- Monitored ORC e-mail and responded to questions about DocuSign and the REDCap Cloud Transition
- Began scanning in and transforming past IRB approved protocols from paper binders to electronic PDFs
- Worked on Research Proposal

6/18/19

- Attended Clinical Research Fellowship class with Dr. Liccardone
    - Included section over data analysis using SPSS
- Monitored DocuSign and completed multiple online re-consents; including signing and compensating
- Re-consented 2 subjects in person; including signing and compensating subject for coming in
- Continued scanning in past IRB approved protocols to electronic PDFs

6/19/19

- Attended seminar over Social Media tips for academic settings
- Monitored DocuSign and completed multiple online re-consents; including signing and compensating
- Continued scanning in past IRB approved protocols to electronic PDFs
- Staff meeting

6/20/19

- Monitored DocuSign and completed multiple online re-consents; including signing and compensating
- Answered phone calls and emails from subjects over DocuSign and the REDCap Cloud transition
- Called subjects to complete surveys over the phone via paper surveys during REDCap cloud transition
- Continued scanning in past IRB approved protocols to electronic PDFs

6/21/19

- Attended Clinical Research Fellowship class with Dr. Liccardone
    - Included discussion of research topics and continued practice with SPSS
- Monitored Docu sign and completed multiple online re-consents; including signing and compensating
- Monitored ORC e-mail and responded to questions about DocuSign and the REDCap Cloud Transition
- Staff meeting to go over basics in the REDCap cloud system
- Completed 9-month survey with subject over the phone

6-24-19

Internship Log

6/24/19

- Attended Presentation: “Vision for the UNTHSC Research Enterprise”
- Monitored ORC e-mail and responded to questions about DocuSign and the REDCap Cloud Transition
- Prepared for the week by noting which subjects needed to be called for surveys and printing paper surveys out for the week
- Completed 9 month survey over the phone via paper survey

6/25/19

- Monitored ORC e-mail and responded to questions about DocuSign and the REDCap Cloud Transition
- Continued preparing charts with paper surveys for the week
- Completed 24 month, 12 month, and 3 21 month surveys over the phone via paper surveys

6/26/19

- Monitored ORC e-mail and responded to questions about DocuSign and the REDCap Cloud Transition
- Called subjects to try and complete surveys or get them scheduled to complete surveys over the phone
- Completed 36 and 24 month surveys over the phone
- Continued scanning past IRB approved protocols to electronic PDFs
- Attended STARs seminar over post-award processes

6/27/19

- Attended Clinical Research Fellow Didactic session
    - Included presentations of research projects and discussion
- Answered phone calls and emails from subjects over DocuSign and the REDCap Cloud transition
- Called subjects to complete surveys over the phone via paper surveys during REDCap cloud transition
- Continued scanning in past IRB approved protocols to electronic PDFs
- Completed 18 month and 9 month survey over the phone

6/28/19

- Attended Clinical Research Fellowship class with Dr. Liccardone
    - Included presentation of my project and discussion
- Monitored ORC e-mail and responded to questions about DocuSign and the REDCap Cloud Transition
- Staff meeting to go over basics in the REDCap cloud system
- Completed 18 month and 9-month surveys with subject over the phone

Cathleen M. Kearns

7-12-19

Internship Log

7/1/19

- Attended Presentation: “Vision for the UNTHSC Research Enterprise”
- Monitored ORC e-mail and responded to questions about DocuSign and the REDCap Cloud Transition
- Prepared for the week by noting which subjects needed to be called for surveys and printing paper surveys out for the week
- Completed two 36 month, two 9 month, and one 12 month surveys over the phone via paper survey

7/2/19

- Monitored ORC e-mail and responded to questions about DocuSign and the REDCap Cloud Transition
- Continued preparing charts with paper surveys for the week
- Completed 3 month and 9 month surveys over the phone via paper surveys
- Scanned IPS IRB approved documents into electronic PDFs

7/3/19

- Monitored ORC e-mail and responded to questions about DocuSign and the REDCap Cloud Transition
- Called subjects to try and complete surveys or get them scheduled to complete surveys over the phone
- Inserted subjects online consent forms from DocuSign into PDF charts

7/4/19

- UNTHSC Closed for July 4th

7/5/19

- Called subjects to try and complete surveys or get them scheduled to complete surveys over the phone
- Inserted subjects online consent forms from DocuSign into PDF charts

Cathleen M. Kearns

7-12-19

Internship Log

7/8/19

- Monitored ORC e-mail and responded to questions about DocuSign and the REDCap Cloud Transition
- Prepared for the week by noting which subjects needed to be called for surveys and printing paper surveys out for the week
- Completed 33 month, and 12 month surveys over the phone via paper survey
- Called subjects to schedule phone surveys
- Staff meeting

7/9/19

- Monitored ORC e-mail and responded to questions about DocuSign and the REDCap Cloud Transition
- Continued preparing charts with paper surveys for the week
- Completed 33 and 15 month surveys over the phone via paper surveys
- Called subjects to schedule phone surveys

7/10/19

- Observed process of downloading approved documents from IRBnet as well as process of making changes to send back to the IRB
- Monitored ORC e-mail and responded to questions about DocuSign and the REDCap Cloud Transition
- Called subjects to try and complete surveys or get them scheduled to complete surveys over the phone
- Completed 3, 15, and 33 month surveys over the phone via paper survey
- Staff meeting

711/19

- Monitored ORC e-mail and responded to questions about DocuSign and the REDCap Cloud Transition
- Completed 3, 9, and 24 month surveys by phone via paper survey
- Called subjects to try and complete surveys or get them scheduled to complete surveys over the phone
- Began extracting recruitment data from subject screening data to see all of the recruitment data for the registry

7/12/19

- Called subjects to try and complete surveys or get them scheduled to complete surveys over the phone
- Continued working on recruitment data as well as looking at the recruitment data in terms of personal research thesis project
- Completed 9 and 24 month surveys by phone via paper survey

Cathleen M. Kearns 8-2-19

Internship Log

7/15/19

- Monitored ORC e-mail and responded to questions about DocuSign and the REDCap Cloud Transition
- Prepared for the week by noting which subjects needed to be called for surveys and printing paper surveys out for the week
- Completed 3, 9, 12, and 18 month surveys over the phone via paper survey
- Called subjects to schedule phone surveys

7/16/19

- Monitored ORC e-mail and responded to questions about DocuSign and the REDCap Cloud Transition
- Continued preparing charts with paper surveys for the week
- Completed 3, 9, 12 and 18 month surveys over the phone via paper surveys
- Called subjects to schedule phone surveys

7/17/19

- Monitored ORC e-mail and responded to questions about DocuSign and the REDCap Cloud Transition
- Called subjects to try and complete surveys or get them scheduled to complete surveys over the phone
- Completed 3, 6, and 18 month surveys over the phone via paper survey
- Resent Docusign consent forms

718/19

- Monitored ORC e-mail and responded to questions about DocuSign and the REDCap Cloud Transition
- Completed 3-month survey by phone via paper survey
- Called subjects to try and complete surveys or get them scheduled to complete surveys over the phone
- Continued working on recruitment data as well as looking at the recruitment data in terms of personal research thesis project

7/19/19

- Called and emailed subjects to try and complete surveys or get them scheduled to complete surveys over the phone
- Completed 24 month surveys by phone via paper survey
- Assisted Cathy with the TCOM Honors research meeting/lunch
- Began research on Pain Biomarkers to assist in future research decisions


8-2-19

Internship Log

7/29/19

- Monitored ORC e-mail and responded to questions about DocuSign and the REDCap Cloud Transition
- Prepared for the week by noting which subjects needed to be called for surveys and printing paper surveys out for the week
- Completed 6 and 12 month surveys over the phone via paper survey
- Completed 30 Month survey in Person via paper survey and re-consented subject
- Called subjects to schedule phone surveys

7/23/19

- Monitored ORC e-mail and responded to questions about DocuSign and the REDCap Cloud Transition
- Continued preparing charts with paper surveys for the week
- Completed two 12 months and 3 month surveys over the phone via paper surveys
- Called and emailed subjects to schedule phone surveys

7/24/19

- Monitored ORC e-mail and responded to questions about DocuSign and the REDCap Cloud Transition
- Called subjects to try and complete surveys or get them scheduled to complete surveys over the phone
- Completed 3,6,9,15, and 18-month surveys by phone via paper surveys
- Sent out letters to remaining subjects that have not re-consented in hopes to update contact information

7/25/19

- Monitored ORC e-mail and responded to questions about DocuSign and the REDCap Cloud Transition
- Completed 15- month survey by phone via paper survey
- Called subjects to try and complete surveys or get them scheduled to complete surveys over the phone
- Continued working on organizing continuing review documents into IRB binder

7/26/19

- Called and emailed subjects to try and complete surveys or get them scheduled to complete surveys over the phone
- Completed 3 and 6 month surveys by phone via paper survey
- Went through process of subject Missing a visit
- Completed the documentation of missed visit for 2 subjects

Cathleen M. Kenna 8-2-19

Internship Log

7/29/19

- Monitored ORC e-mail and responded to questions about DocuSign and the REDCap Cloud Transition
- Prepared for the week by noting which subjects needed to be called for surveys and printing paper surveys out for the week
- Completed 6 and 12 month surveys over the phone via paper survey
- Completed 30 Month survey in Person via paper survey and re-consented subject
- Called subjects to schedule phone surveys

7/30/19

- Monitored ORC e-mail and responded to questions about DocuSign and the REDCap Cloud Transition
- Continued preparing charts with paper surveys for the week
- Completed two 12 months and 3 month surveys over the phone via paper surveys
- Called and emailed subjects to schedule phone surveys

7/31/19

- Monitored ORC e-mail and responded to questions about DocuSign and the REDCap Cloud Transition
- Called subjects to try and complete surveys or get them scheduled to complete surveys over the phone
- Completed 3,6,9,15, and 18-month surveys by phone via paper surveys
- Sent out letters to remaining subjects that have not re-consented in hopes to update contact information

8/1/19

- Monitored ORC e-mail and responded to questions about DocuSign and the REDCap Cloud Transition
- Completed 30 and 15- month surveys by phone via paper survey
- Called subjects and sent emails to try and complete surveys or get them scheduled to complete surveys over the phone
- Began working project thesis by formatting the document and writing the introduction

8/2/19

- Called and emailed subjects to try and complete surveys or get them scheduled to complete surveys over the phone
- Completed 6 and 12 month surveys by phone via paper survey
- Went through process of subject Missing a visit
- Continued working on project Thesis

Cathleen M. Kenna 8-2-19

Internship Log

8/5/19

- Monitored ORC e-mail and responded to questions about DocuSign and the REDCap Cloud Transition
- Met with Cathy to discuss internship and project progress
- Prepared for the week by noting which subjects needed to be called for surveys
- Completed 6 and 9 month surveys over the phone via paper survey
- RedCap cloud training

8/6/19

- RedCap cloud launch to current subjects
- Monitored ORC e-mail and responded to questions about DocuSign and the REDCap Cloud Transition
- Completed 3, 12 and 15 month surveys over the phone via RedCap
- Staff meeting to go over processes to complete RedCap migration
- Began entering in subject information (such as birthday and clincard number) to RedCap cloud

8/7/19

- Monitored ORC e-mail and responded to questions about DocuSign and the REDCap Cloud Transition
- Continued entering in subject information to RedCap
- Disscussion with Cathy over how to deal with date abnormalities in context of the transition to RedCap; abnormalities that we found were double surveys, wrong date input, or wrong subject number input
- Began data entry of paper surveys into RedCap

8/8/19

- Monitored ORC e-mail and responded to questions about DocuSign and the REDCap Cloud Transition
- Continued data entry of paper surveys and entering subject information

8/9/19

- Cathy approved day off for family matter

9-18-19

Internship Log

8/19/19

- Monitored ORC e-mail and responded to questions about DocuSign and the REDCap Cloud Transition
- Completed 12 and 27 month phone surveys via RedCap
- Reviewed processes and procedures for enrolling subjects in Seed Grant SPADE project

8/20/19

- Monitored ORC e-mail and responded to questions about DocuSign and the REDCap Cloud Transition
- Completed 6, 9,12, and 18 month surveys by phone via RedCap
- Monitored online surveys that came in and completed payment process
- Observed SPADE project enrollment process with subject

8/21/19

- Monitored ORC e-mail and responded to questions about DocuSign and the REDCap Cloud Transition
- Completed 18 and 24 month surveys over the phone via RedCap
- Completed SPADE enrollment process with subject In-person
- Observed process of electronic consent of a new subject
    - Including signing documents in DocuSign, entering information into RedCap, and sending out salvia kit and Clincard through EShip global

8/22/19

- Monitored ORC e-mail and responded to questions about DocuSign and the REDCap Cloud Transition
- Reviewed protocol to ensure that new procedures are in place for remote consenting
- Completed 15 month survey by phone via RedCap
- Completed SPADE enrollment process with subject online
-

8/23/19

- Monitored ORC e-mail and responded to questions about DocuSign and the REDCap Cloud Transition
- Continued calling subjects to complete or schedule phone surveys
- Staff meeting to go over RedCap tracking, new seed grant, procedure for new subjects in RedCap and any other RedCap questions

9-18-19

Internship Log

8/19/19

- Monitored ORC e-mail and responded to questions about DocuSign and the REDCap Cloud Transition
- Completed 12 and 27 month phone surveys via RedCap
- Reviewed processes and procedures for enrolling subjects in Seed Grant SPADE project

8/20/19

- Monitored ORC e-mail and responded to questions about DocuSign and the REDCap Cloud Transition
- Completed 6, 9,12, and 18 month surveys by phone via RedCap
- Monitored online surveys that came in and completed payment process
- Observed SPADE project enrollment process with subject

8/21/19

- Monitored ORC e-mail and responded to questions about DocuSign and the REDCap Cloud Transition
- Completed 18 and 24 month surveys over the phone via RedCap
- Completed SPADE enrollment process with subject In-person
- Observed process of electronic consent of a new subject
    - Including signing documents in DocuSign, entering information into RedCap, and sending out salvia kit and Clincard through EShip global

8/22/19

- Monitored ORC e-mail and responded to questions about DocuSign and the REDCap Cloud Transition
- Reviewed protocol to ensure that new procedures are in place for remote consenting
- Completed 15 month survey by phone via RedCap
- Completed SPADE enrollment process with subject online
- Attended online meeting with Cathy and RedCap programmer to discuss system issues

8/23/19

- Monitored ORC e-mail and responded to questions about DocuSign and the REDCap Cloud Transition
- Completed electronic consent of new subject including signing documents, entering information into RedCap and mailing out salvia kit and Clincard.
- Observed the enrollment process of in-person subjects
    - Enrolled 1st subject in-person in new RedCap system

Cathleen M. Kearns 9-18-19

Internship Log

8/26/19

- Monitored ORC e-mail and responded to questions about DocuSign and the REDCap Cloud Transition
- Completed 21 and 24 month surveys in-person via RedCap
- Monitored online surveys that came in and completed payment process
- Complete SPADE project enrollment process with subject in person
- Resent links and sent reminder emails out for subjects that were coming to the end of time window to complete survey

8/27/19

- Monitored ORC e-mail and responded to questions about DocuSign and the REDCap Cloud Transition
- Completed 2 subject electronic consent process and mailed out salvia kit
- Worked on internship thesis project

8/28/19

- Monitored ORC e-mail and responded to questions about DocuSign and the REDCap Cloud Transition
- Completed 12 month survey over the phone via RedCap
- Worked on internship thesis project
    - Began data analysis of Facebook data including post engagement and screening data from each post

8/29/19

- Monitored ORC e-mail and responded to questions about DocuSign and the REDCap Cloud Transition
- Completed 12, 15, and 21 month surveys by phone via RedCap
- Completed SPADE enrollment process with subject online
- Observed process of enrolling subject after salvia kit is received
    - Including entering information in RedCap, registering subject clincard in Greenphire, and generating subject survey schedule

8/30/19

- Monitored ORC e-mail and responded to questions about DocuSign and the REDCap Cloud Transition
- Completed electronic consent of new subject including signing documents, entering information into RedCap and mailing out salvia kit and Clincard.
- Monitored online surveys that came through and completed payment process
- Completed 39 month survey by phone via RedCap
- Attended meeting to discuss possible social media recruitment ideas for the study

9-18-19

Internship Log

9/2/19

- UNTHSC Closed for Labor Day

9/3/19

- Monitored ORC e-mail and responded to questions
- Completed 2 subject electronic consent process and mailed out salvia kit
- Worked on internship thesis project
- Brainstormed possible recruitment ideas
- Contacted multiple school districts to ask about possible advertising for study recruitment
- Contacted Subjects who were coming to the end of their survey window

9/4/19

- Monitored ORC e-mail and responded to questions
- Completed 6 and 12 month survey over the phone via RedCap
- Completed SPADE enrollment process with subject in-person
- Completed registry enrollment process for subject by entering information in RedCap and registering Clincard
- Monitored online surveys that came through and completed payment process

9/5/19

- Monitored ORC e-mail and responded to questions
- Completed 21 Month survey by phone via RedCap
- Completed SPADE enrollment process with subject online
- Completed registry enrollment process for subject by entering information in RedCap and registering Clincard
- Contacted multiple cities across the State for possible advertisement/ recruitment opportunities
- Delivered returned salvia kits down to the lab

9/6/19

- Monitored ORC e-mail and responded to questions
- Completed electronic consent of new subject including signing documents, entering information into RedCap and mailing out salvia kit and Clincard.
- Contacted subjects that have not completed online surveys and subjects that needed to schedule phone surveys
- Completed 12 and 18 month surveys by phone via RedCap

9-18-19

Internship Log

9/9/19

- Monitored ORC e-mail and responded to questions
- Completed 12, 21 and 33-month phone surveys
- Contacted Subjects who were coming to the end of their survey window
- Compensated subjects for surveys completed over the weekend

9/10/19

- Monitored ORC e-mail and responded to questions
- Monitored screening forms that came in to insure no one had any additional questions
- Completed 1 subject electronic consent process and mailed out salvia kit
- Brainstormed possible recruitment ideas

9/11/19

- Monitored ORC e-mail and responded to questions
- Monitored screening forms that came in to insure no one had any additional questions
- Completed 9 survey over the phone via RedCap
- Completed SPADE enrollment process with subject online
- Brainstormed and researched possible recruitment ideas
- Worked on internship project

9/12/19

- Monitored ORC e-mail and responded to questions
- Completed 9 Month survey by phone via RedCap
- Delivered returned salvia kits down to the lab
- Worked on internship thesis project

9/13/19

- Monitored ORC e-mail and responded to questions
- Called and left messages with subjects that have not yet reconsented and mailed out reconsent packets by mail
- Contacted subjects that have not completed online surveys and subjects that needed to schedule phone surveys
- Completed 18, 21 and 24 month surveys by phone via RedCap
- Staff meeting over updates

9.27.19

Internship Log

9/16/19

- Monitored ORC e-mail and responded to questions
- Completed 9, and 33-month phone surveys
- Contacted contact at radio station for possible advertisement opportunities
- Contacted Subjects who were coming to the end of their survey window
- Compensated subjects for surveys completed over the weekend

9/17/19

- Monitored ORC e-mail and responded to questions
- Monitored screening forms that came in to insure no one had any additional questions
- Completed 1 subject electronic consent process and mailed out salvia kit
- Staff meeting to discuss community event for Spring 2019
- Data analysis session

9/18/19

- Monitored ORC e-mail and responded to questions
- Monitored screening forms that came in to insure no one had any additional questions
- Completed 6 and 9 survey over the phone via RedCap
- Worked on internship project

9/19/19

- Monitored ORC e-mail and responded to questions
- Delivered returned salvia kits down to the lab
- Worked on internship thesis project
- Monitored SPADE surveys that were completed

9/20/19

- Monitored ORC e-mail and responded to questions
- Contacted subjects that have not completed online surveys and subjects that needed to schedule phone surveys
- Completed 3 SPADE follow-up surveys by phone via RedCap
- Completed 15 and 30 month surveys by phone via RedCap
- Meeting with marketer from Bass hall as possible recruitment idea

9.27.19

Internship Log

9/23/19

- Monitored ORC e-mail and responded to questions
- Completed 12 and 30-month phone surveys
- Completed 2 SPADE follow-up surveys over the phone
- Contacted Subjects who were coming to the end of their survey window
- Compensated subjects for surveys completed over the weekend

9/24/19

- Monitored ORC e-mail and responded to questions
- Monitored screening forms that came in to insure no one had any additional questions
- Meeting with Dr. Licciardone to go over Thesis Data analysis
- Worked on Thesis project

9/25/19

- Monitored ORC e-mail and responded to questions
- Monitored screening forms that came in to insure no one had any additional questions
- Completed 9 and 33 survey over the phone via RedCap
- Worked on internship project

9/26/19

- Monitored ORC e-mail and responded to questions
- Completed In-Person Baseline appointment including informed consent
- Completed SPADE Follow-up survey over the phone
- Worked on internship thesis project
- Sent out SPADE charts to subjects in Group 2 timeframe

9/27/19

- Monitored ORC e-mail and responded to questions
- Contacted subjects that have not completed online surveys and subjects that needed to schedule phone surveys
- Revising edits on Thesis project

9.27.19

Internship Log

9/30/19

- Monitored ORC e-mail and responded to questions
- Completed 12 month phone surveys
- Contacted Subjects who were coming to the end of their survey window
- Compensated subjects for surveys completed over the weekend
- Completed enrollment process for 2 subjects after salvia kit was returned

10/01/19

- Monitored ORC e-mail and responded to questions
- Monitored screening forms that came in to insure no one had any additional questions
- Consented 2 subjects online via DocuSign and sent out salvia kits
- Meeting to discuss upcoming community event

10/02/19

- Monitored ORC e-mail and responded to questions
- Monitored screening forms that came in to insure no one had any additional questions
- Consented 3 subjects online via DocuSign and sent out salvia kits
- Insured all subjects with phone visits were scheduled on the calendar

10/03/19

- Monitored ORC e-mail and responded to questions
- Monitored screening forms that came in to insure no one had any additional questions
- Consented 2 subjects online via DocuSign and sent out salvia kits
- Sent out SPADE charts to subjects in Group 2 timeframe
- Delivered returned salvia kits to genetics lab

10/04/19

- Monitored ORC e-mail and responded to questions
- Monitored screening forms that came in to insure no one had any additional questions
- Consented 1 subject online via DocuSign and sent out salvia kits
- Completed 18 month survey by phone
- Completed enrollment process for 1 subject after salvia kit returned

10.16.19

Internship Log

10/07/19

- Monitored ORC e-mail and responded to questions
- Completed 12 month phone surveys
- Contacted Subjects who were coming to the end of their survey window
- Compensated subjects for surveys completed over the weekend
- Completed enrollment process for 2 subjects after salvia kit was returned
- Meeting with Dr. Dory to discuss thesis revisions
- Worked on thesis presentation slides

10/08/19

- Monitored ORC e-mail and responded to questions
- Monitored screening forms that came in to insure no one had any additional questions
- Worked on thesis revisions and presentation slides
- Enrolled 1 subject after salvia kit was returned

10/09/19

- Monitored ORC e-mail and responded to questions
- Monitored screening forms that came in to insure no one had any additional questions
- Completed 6 month survey by phone
- Completed SPADE follow-up survey by phone
- Thesis defense practice session with ORC team

10/10/19

- Monitored ORC e-mail and responded to questions
- Monitored screening forms that came in to insure no one had any additional questions
- Completed 15 month survey by phone
- Completed IRB approved Re-Consent by phone with fellow coordinators
- Worked on thesis revisions

10/11/19

- Monitored ORC e-mail and responded to questions
- Monitored screening forms that came in to insure no one had any additional questions
- Completed enrollment process for 1 subject after salvia kit returned
- Worked on thesis revisions

10.16.19

Internship Log

10/14/19

- Monitored ORC e-mail and responded to questions
- Completed 9 month phone survey and 30 month survey in person
- Contacted Subjects who were coming to the end of their survey window
- Compensated subjects for surveys completed over the weekend
- Worked on thesis project revisions

10/15/19

- Monitored ORC e-mail and responded to questions
- Monitored screening forms that came in to insure no one had any additional questions
- Enrolled 1 subject after salvia kit was returned
- Completed 18 and 24 month surveys by phone
- Worked on thesis project revisions

10/16/19

- Monitored ORC e-mail and responded to questions
- Monitored screening forms that came in to insure no one had any additional questions
- Completed 9 month survey by phone
- Team phone conference with contact at KLTY to discuss possible promotional event
- Finished thesis revision and sent project to committee

10/17/19

- Monitored ORC e-mail and responded to questions
- Monitored screening forms that came in to insure no one had any additional questions
- Completed online consent for SPADE sub-study and enrolled subject into sub-study
- Completed re-consent process with subject in person
- Completed 27 month survey by phone
- Delivered returned saliva kits to ORC lab team

10/18/19

- Monitored ORC e-mail and responded to questions
- Monitored screening forms that came in to insure no one had any additional questions
- Completed enrollment process for 2 subject after salvia kit returned
- Put out and organized paper flyers in the UNTHSC Clinic

11-11-19

Internship Log

10/21/19

- Monitored ORC e-mail and responded to questions
- Completed 12 month phone survey
- Compensated subjects for surveys completed over the weekend
- Contacted subjects to schedule phone surveys for the week

10/22/19

- Monitored ORC e-mail and responded to questions
- Monitored screening forms that came in to insure no one had any additional questions
- Enrolled 1 subject after salvia kit was returned
- Completed 30 survey by phone

10/23/19

- Monitored ORC e-mail and responded to questions
- Monitored screening forms that came in to insure no one had any additional questions
- Completed 30 month survey by phone
- Practice defense presentation with Cathy
- Completed 2 electronic consent forms and sent out saliva kits

10/24/19

- Monitored ORC e-mail and responded to questions
- Monitored screening forms that came in to insure no one had any additional questions
- Completed online consent for SPADE sub-study and enrolled subject into sub-study
- Completed 12 and 18 month surveys by phone
- Delivered returned saliva kits to ORC lab team

10/25/19

- Monitored ORC e-mail and responded to questions
- Monitored screening forms that came in to insure no one had any additional questions
- Completed 33 month visit in-person
- Completed HIPAA form in-person
- Completed 12 month survey by phone
- Completed weekly recruitment report for Dr. Licciardone

11-11-19

Internship Log

Week 22: 10/28-11/1: Out of office for medical emergency

11/4/19

- Monitored ORC e-mail and responded to questions
- Compensated subjects for surveys completed over the weekend
- Completed weekly Recruitment report for previous week
- Attended defense for fellow CRM intern

11/5/19

- Monitored ORC e-mail and responded to questions
- Monitored screening forms that came in to insure no one had any additional questions
- Completed 9 and 21 month surveys by phone
- Staff meeting to discuss recruitment strategies and other research concerns

11/6/19

- Monitored ORC e-mail and responded to questions
- Monitored screening forms that came in to insure no one had any additional questions
- Completed 9, 12, 18, 27, and 30 month surveys by phone
- Completed 3 electronic consent forms and sent out saliva kits

11/7/19

- Monitored ORC e-mail and responded to questions
- Monitored screening forms that came in to insure no one had any additional questions
- Completed 12 month survey by phone
- Consented and enrolled subject in-person including completing survey and obtaining informed consent
- Assisted in enrolling subject in person by completed the enrolment process

11/8/19

- Monitored ORC e-mail and responded to questions
- Monitored screening forms that came in to insure no one had any additional questions
- Completed 2 online consent forms and sent out saliva kits
- Completed weekly recruitment report for Dr. Licciardone
- Practice defense presentation with Cathy

11-11-19

Internship Log

11/11/19

- Monitored ORC e-mail and responded to questions
- Compensated subjects for surveys completed over the weekend
- Completed In-person baseline appointment including informed consent
- Completed 36 month survey by phone

11/12/19

- Monitored ORC e-mail and responded to questions
- Monitored screening forms that came in to insure no one had any additional questions
- Completed 15 month survey by phone
- Completed 2 electronic informed consent via DocuSign

11/13/19

- CRM Thesis Defense
- Worked on Thesis revisions
- Completed 18 month survey by phone

11/14/19

- Monitored ORC e-mail and responded to questions
- Monitored screening forms that came in to insure no one had any additional questions
- Completed 33 Month and 18 month surveys by phone
- Worked on Final Thesis revisions

11/15/19

- Worked on and completed Final Thesis revisions

Cathleen M. Kearns 11-18-19

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