

**Association of Pain Sensitivity with Outcome Measures for Quality of Life,
Functional Ability and Current Pain Intensity in Chronic Low Back Pain**

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Pain sensitivity, as measured by the self-reported Pain Sensitivity Questionnaire (PSQ), was investigated using data from the PRECISION Pain Research Registry. Outcome measures for quality of life, functional ability, and current pain intensity were found to be significantly associated with PSQ Total in participants reporting chronic low back pain, even when controlling for age, sex, race, ethnicity, smoking status, and body mass index. Higher reported pain sensitivity correlated with reported higher pain intensity, lower quality of life, and increased physical disability.

I. Introduction

Pain is a neurobiological sensation that is modulated by numerous factors, both physical and psychological, and is a subjective experience that varies even within the same individual. Acutely it can provide warning of abnormality or trauma, but chronic pain can potentially result in pathological states such as central sensitization where neural alterations result in generalized hypersensitivity to physical stimuli that can greatly exacerbate discomfort (Woolf 2011). The perception of pain can vary by attention, mood and circumstance but some individuals have a regular heightened state of pain hypersensitivity that can be a risk factor for other comorbidities (Woolf 2011).

Increased pain sensitivity is also a known risk factor for developing chronic pain disorders and has been shown to be a generalized increase in pain perception in chronic pain patients thought to be the result of a dysfunction in endogenous pain inhibitory systems (Ruscheweyh 2012). Central sensitization originates in the central nervous system which causes numerous changes in pain sensation that can increase sensitivity to ordinary inputs since it is no longer solely the result of peripheral stimuli resulting in a heightened response (Latremoliere and Woolf 2009).

Chronic pain itself is associated with numerous comorbidities including the symptom cluster of sleep disturbance, pain, anxiety, depression, and low energy or fatigue (SPADE), where numerous facets of an individual's life can be altered from bidirectional symptom relationships. Perception of pain can be enhanced for various reasons including psychological. Factors such as depression or anxiety affecting the pain experience with higher levels of pain intensity and are a significant risk factor for developing chronic physical disability (Linton 2011). Using chronic low back pain participants from the Pain Registry for Epidemiological, Clinical and Interventional Studies and Innovation (PRECISION) Pain Research Registry, this study examined the relationship of reported pain sensitivity questionnaire scores to other outcome measures the SPADE cluster, pain intensity, and physical function.

The pain sensitivity questionnaire (PSQ) is a validated measure of self-reporting that strongly correlates with experimental pain sensitivity scores in both healthy controls and those suffering from chronic pain (Ruscheweyh 2012). It is a survey of 17 questions that asks an individuals to imagine a scenario of common daily life and rate what they imagine the pain of the situation would invoke on a scale of 0 to 10, with 0 meaning they did not think it would be painful and 10 meaning the most pain imaginable. The imagined scenarios range from things that typically do not result in the experience of pain like a lukewarm shower to unexpected accidents that could routinely happen such as walking into a glass coffee table. A total score is calculated from the painful criteria while the painless criteria serves as a control score. PSQ can be further divided into mild and moderate sub scores by categorizing questions thought to produce less or more pain.

II. Internship Project

a. Background

Sleep disturbance and chronic pain are common comorbidities in a potential bidirectional relationship, where the hyperalgesic effect of partial sleep deprivation is may be related to impairments of the pain modulatory systems, which may further create an attenuated effect on analgesic medications (Okifuji 2011). This could impact chronic pain patients who frequently suffer from sleep problems as well as their pain management strategies if medication dosages have to be adjusted due to the lack of restful sleep.

Alterations in perceived pain sensitivity related to poor quality of sleep have also been noted in extensive studies. In a cross-sectional study comparing self-reported measures of sleep with experimental pain sensitivity tests, all sleep parameters except duration were significantly associated with reduced pain tolerance (Siversten et al 2015). In an experimental study on the effect of sleep disturbance on pain processing, subjects with primary insomnia had significantly reduced pain thresholds and reported episodes of spontaneous pain when at home (Haack et al 2012). In an experimental study, patients with chronic low back pain had significantly increased pain sensitivity with greater aftersensations and the pain sensitivity was associated with increased pain catastrophizing and a recent history of higher pain intensity (Meints et al 2019).

Patients with chronic pain tend to have a lower quality of life with symptoms that commonly appear in clusters, but improvement of the SPADE symptom cluster burden in chronic musculoskeletal pain patients predicted functional improvement at later regular follow-up intervals (Davis et al 2016). The SPADE symptoms are typically concurrent, where only 1 in 10 patients experienced a single symptom in the same study (Davis 2016). In a cross-sectional study for pain sensitivity and depression, when adjusted for sleep disturbance and physical

inactivity, patients with depression had significant higher PSQ-minor scores that could be predicted by severity of anxiety symptoms (Hermesdorf et al 2016).

PSQ strongly correlates with experimentally derived pain intensity ratings in healthy subjects and chronic pain patients, with chronic pain patients reporting significantly elevated PSQ scores (Ruscheweyh 2012). Imaging studies have demonstrated that higher pain intensity ratings are associated with larger cerebral activation in pain processing areas of the brain, indicating physical differences in pain intensity variance (Ruscheweyh 2012). PSQ has been utilized in one study to evaluate chronic pain patients alongside the central sensitization inventory where significant differences were reported between chronic pain patients with and without central sensitization syndrome (Tuna et al 2018).

b. Specific Aim

The aim of this study was to investigate the potential relationship PSQ scores have with other outcome measures in subjects reporting chronic pain. Identifying these types of relationships will help us determine if higher pain sensitivity corresponds with higher reported pain intensity, greater physical disability and lower quality of life. We hypothesize that in subjects with chronic low back pain, pain sensitivity scores will be positively correlated with current pain intensity as measured by the Numerical Rating Scale (NRS) for pain, quality of life as measured reported using the SPADE symptom cluster and physical functional ability by the as measured Roland-Morris Questionnaire (RMDQ). To achieve this aim, we have compared baseline PSQ scores using three analyses of PSQ on NRS, PSQ on RMDQ, and PSQ on SPADE. Each analysis controlled for the variables of age, gender, race, ethnicity, smoking status, and body mass index (BMI).

c. Significance

Pain is normal part of life, but chronic pain can be a debilitating condition that impairs everyday activities and overall quality of life. Chronic pain is estimated by the Center for Disease Control to have a prevalence of 20.4% of adults, 8% of which are classified as having high-impact chronic pain that causes substantial life limitations (Dahlhamer et al 2016). Chronic pain and other symptoms such as depression frequently occur together with prevalence approximating 30-50% in the United States (Kroenke et al 2011). Chronic pain can exacerbate physical stimuli sensations and decrease pain thresholds with increased synaptic function of nociceptive neurons activated by the central nervous system resulting in pain hypersensitivity (Latremoliere and Woolf 2009).

Chronic pain patients that exhibit high experimental pain sensitivity are also known to respond comparatively worse to medical treatment than to those with lower experimental pain sensitivities (Ruscheweyh 2009). Chronic pain patients have also been shown to have significantly elevated PSQ scores when compared to healthy controls, consistent with enhanced pain perception (Ruscheweyh 2012). Differences in pain sensitivity could potentially be linked to poor outcomes whereas knowledge of increased pain sensitivity in chronic pain patients may prompt identification of those with enhanced perception of pain and different pain management plans.

d. Materials and Methods

Data was utilized from the PRECISION Pain Research Registry where participants suffering from chronic low back pain have been recruited from numerous sources, including locally in the Fort Worth area and across the Contiguous United States using social media advertisements. Participants are able to complete surveys online or over the telephone.

In order to enroll in the registry, prospective participants must be able to communicate and be able to respond to surveys in English; must be between the ages of 21-79 years; must report having low back pain for three months or longer and must report having low back pain for at least half of the days of the past six months; and must report currently having a physician for at least one month. Prospective participants must live in the Contiguous United States or the District of Columbia. People who are pregnant, institutionalized, or incarcerated are excluded from participating in the study.

The PRECISION Pain Registry currently has 1089 cases as of March 12, 2021, of which 494 were included in the analysis based on having PSQ data available at baseline. The survey metric for PSQ was added at a later point in the registry, so not all cases completed it upon initial enrollment. In a study that originally validated the use of PSQ scores in patients suffering from chronic pain, participants were shown to have a significantly higher PSQ total score of 4.1 ± 1.7 when compared to healthy controls of 3.4 ± 1.1 (Ruschewyeh 2012). Participants in the PRECISION Pain Registry had an average PSQ total score of 4.3 ± 2 (**Table 1**), consistent with the results of the earlier study.

Table 1. PRECISION Demographics Range and Mean

	N	Minimum	Maximum	Mean	Std. Deviation
AGE	494	21	79	52.08	13.565
BMI	494	15.4	61.9	31.907	8.1055
PSQ (Total)	494	.9	10.0	4.280	2.0087
NRS	494	0	10	6.06	1.796
RMDQ Score	494	1	24	14.56	5.767
SPADE Score	494	41.4	76.4	58.830	6.7110
Valid N (listwise)	494				

The PRECISION Pain Registry collects baseline data on cases for PSQ, SPADE, RMDQ, and NRS with quarterly follow-up for a period of one year. Pain sensitivity questionnaire scores and NRS scores are ordinal measurements with a range of 0-10, but PSQ becomes continuous when scores are calculated with a total, moderate and minor score. The variable, PSQ Total, was the score focused on for this analysis due to its inclusion of the full pain sensitivity criteria, and the moderate and minor scores are created from a selected division of specific questions. RMDQ is a 24-point scale and SPADE is a continuous measurement.

Table 2. PRECISION Demographics of Sex and Ethnicity

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Male	136	27.5	27.5	27.5
	Female	358	72.5	72.5	100.0
	Hispanic	30	6.1	6.1	6.1
	Non-Hispanic	464	93.9	93.9	100.0

This study is a cross-sectional design that uses data from cases at the baseline encounter to compare PSQ scores with three analyses, the effect of PSQ on NRS, PSQ on RMDQ, and PSQ on SPADE. Each analysis controlled for the variables of age, sex, race, ethnicity, smoking status, and BMI. Of the included 494 PRECISION Pain Registry participants, the average age was 52 with a reported BMI of 32 and 73% were female (**Tables 1 and 2**). In the study population, 85% of participants reported being Caucasian, 12% African American, 1% Native American, 1% Asian, and 0.2% Pacific Islander (**Table 3a**). The total number of participants in each of the five groups were insufficient for data analysis without combining groups (**Table 3b**). Smoking status was likewise combined into current and nonsmoker (**Tables 4a and 4b**).

Data analysis was performed using multiple linear regression utilizing IBM SPSS Statistics 25, and *p*-values less than 0.05 were considered significant.

Table 3a. PRECISION Demographics of Race

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Native American	5	1.0	1.0	1.0
	Asian	6	1.2	1.2	2.2
	African American	60	12.1	12.1	14.4
	Pacific Islander	1	.2	.2	14.6
	Caucasian	422	85.4	85.4	100.0
	Total	494	100.0	100.0	

Table 3b. PRECISION Demographics of Race Transformation

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Other	72	14.6	14.6	14.6
	Caucasian	422	85.4	85.4	100.0
	Total	494	100.0	100.0	

Table 4a. PRECISION Demographics of Smoking History

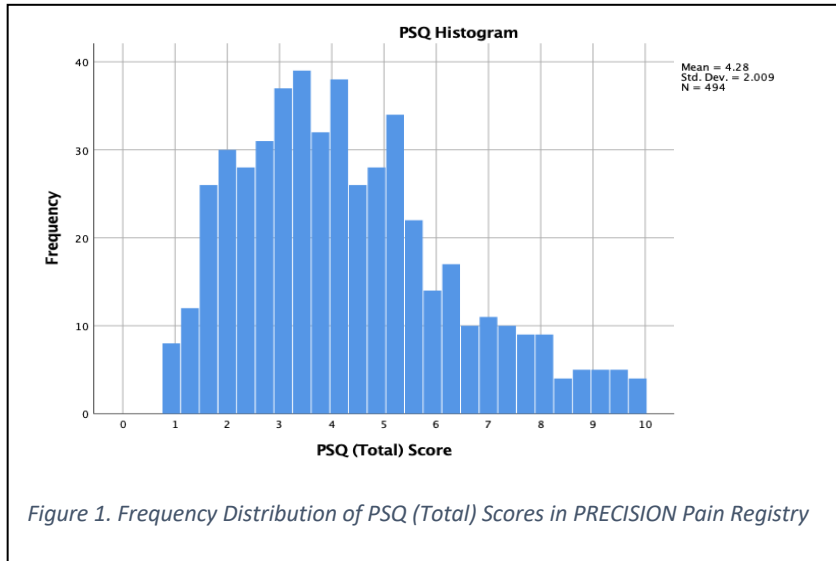
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Nonsmoker	252	51.0	51.0	51.0
	Current	78	15.8	15.8	66.8
	Former	164	33.2	33.2	100.0
	Total	494	100.0	100.0	

Table 4b. PRECISION Demographics of Smoking History Transformation

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Current	78	15.8	15.8	15.8
	Nonsmoker or Former	416	84.2	84.2	100.0
	Total	494	100.0	100.0	

e. Results and Discussion

Correlation and multiple linear regression analyses were used to examine the relationships



between PSQ and NRS, PSQ and RMDQ, and PSQ and SPADE. PSQ (Total) was observed to be skewed to the right on histogram violating normal assumption (**Figure 1**), but the sample size used was large and both

parametric and nonparametric tests produced similar results (**Table 5**). PSQ (Total) scores were significantly positively correlated with NRS ($r = 0.388$), RMDQ ($r = 0.266$), and SPADE ($r = 0.258$, all of which with p -values < 0.001), indicating as reported pain sensitivity scores increased so did reported pain intensity, impaired physical function, and lower quality of life.

Table 5. Correlation Analysis between PSQ and Outcome Variables

		PSQ (Total) Score	NRS	RMDQ Score	SPADE Score
PSQ (Total) Score	Pearson Correlation	1	.388**	.266**	.258**
	Sig. (2-tailed)		.000	.000	.000
	N	494	494	494	494
PSQ (Total) Score	Spearman's Rho Correlation	1.000	.361**	.241**	.237**
	Sig. (2-tailed)		.000	.000	.000
	N	494	494	494	494

Table 6. Multiple Regression Model of PSQ and NRS Controlling for Variables

Model	Unstandardized Coefficients		Standardized Coefficients	t	Sig.	
	B	Std. Error	Beta			
1	(Constant)	4.783	.809		5.910	.000
	PSQ (Total) Score	.288	.041	.322	7.067	.000
	AGE	.007	.006	.051	1.198	.232
	GENDER	.123	.166	.031	.745	.457
	RACE_REG	-.502	.227	-.099	-2.213	.027
	ETHNICITY	.087	.316	.012	.275	.783
	SMOKING_REG	-.810	.208	-.165	-3.902	.000
	BMI	.013	.009	.060	1.443	.150

Multiple linear regression models analyzed the relationship between PSQ and NRS, PSQ and RMDQ, and PSQ and SPADE when controlling for the confounding variables of age, sex, race, ethnicity, smoking status, and BMI. The PSQ (Total) score remained significant in all models, accounting for 18.8% of the variance in NRS ($F(7, 486) = 16.117, p < 0.001$), 13.6% of the variance in RMDQ ($F(7, 486) = 10.933, p < 0.001$), and 13% of the variance in SPADE ($F(7, 486) = 10.395, p < 0.001$). As PSQ (Total) increased by one unit, NRS increased by 0.288,

RMDQ increased by 0.69, and SPADE increased by 0.967 in their respective models (**Tables 6-8**).

Table 7. Multiple Regression Model of PSQ and RMDQ Controlling for Variables

Model	Unstandardized Coefficients		Standardized Coefficients	t	Sig.
	B	Std. Error	Beta		
1 (Constant)	5.974	2.680		2.229	.026
PSQ (Total) Score	.690	.135	.240	5.117	.000
AGE	.023	.019	.054	1.216	.225
GENDER	.826	.548	.064	1.506	.133
RACE_REG	.366	.752	.022	.487	.627
ETHNICITY	1.057	1.047	.044	1.009	.313
SMOKING_REG	-3.249	.688	-.206	-4.722	.000
BMI	.106	.031	.149	3.481	.001

Table 8. Multiple Regression Model of PSQ and SPADE Controlling for Variables

Model	Unstandardized Coefficients		Standardized Coefficients	t	Sig.
	B	Std. Error	Beta		
1 (Constant)	54.871	3.130		17.532	.000
PSQ (Total)	.967	.157	.290	6.147	.000
AGE	-.086	.022	-.174	-3.915	.000
GENDER	.438	.640	.029	.684	.494
RACE_REG	1.858	.878	.098	2.117	.035
ETHNICITY	1.141	1.223	.041	.933	.351
SMOKING_REG	-2.813	.803	-.153	-3.502	.001
BMI	.066	.036	.080	1.852	.065

The PSQ and NRS model also showed a significant contribution from race ($p = 0.027$) and smoking status ($p < 0.001$), where subjects reporting race other than Caucasian or a current smoking history had lower pain intensity. The PSQ and RMDQ scores also showed a significant contribution from smoking status ($p < 0.001$) and BMI ($p = 0.001$), where subjects reporting current smoking history have lower physical disability and those with a higher BMI have worse

scores on these instruments. PSQ and SPADE also showed a significant contribution from age ($p < 0.001$), race ($p = 0.035$) and smoking status ($p = 0.001$), where older participants or current smoking history report higher quality of life, and subjects reporting race other than Caucasian as having a lower quality of life. The small to medium analgesic effects of nicotine and tobacco have been documented and could be more rewarding in subjects experiencing chronic pain but were previously associated with more severe chronic pain and overall physical impairment (Ditre 2016). Race and lower pain intensity and lower quality of life could be the result of health disparities that can affect overall health outcomes (Negussie 2017).

The present study supports previous efforts that demonstrated generalized increased pain perception is associated with other comorbidities and risk factors. In the PRECISION Pain Research Registry, increased reported pain sensitivity was significantly correlated with higher reported pain intensity scores, greater presence of indicators signifying lower quality of life and greater degrees of physical disability. A future direction is to look specifically into central sensitization, which could be measured from the Centralization Sensitization Inventory (CSI), a validated self-reported outcome measure that quantifies central sensitization symptom severity (Scerbo et al 2018). The PSQ Total scores could then be compared with CSI, or it could be used as an additional confounding variable for which to control.

f. Bibliography

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III. Internship Experience

a. Internship Site

The internship practicum project was completed over the fall and spring semesters in The Osteopathic Research Center in the Department of Family Medicine at the University of North Texas Health Science Center. Dr. Licciardone is the site principal investigator, and Ms. Cathy Kearns is the practicum site mentor. Samantha Johnson provided day-to-day guidance related to research procedures for this study. The project utilized existing data from the Pain Registry for Epidemiological, Clinical, and Interventional Studies and Innovation (PRECISION Pain Research Registry), which is an observational study of chronic low back pain that collects longitudinal data using validated research instruments and biological samples for genetic analysis.

b. Journal Summary

I participate in The Osteopathic Research Center PRECISION Pain Research Registry as an intern and worked on tasks such as assembling mailing kits, data entry for subject enrollment in REDCap Cloud and subject compensation in Greenhire, delivery of saliva samples to the lab and making phone calls to subjects as reminders to complete the survey or assistance to do so over the telephone. I attended regular staff meetings and observed discussions related to a wide

range of research administrative issues including end of fiscal year budgeting issues, software operational issues, troubleshooting and resolving software issues, Institutional Review Board policies and procedures, and general research administration processes.

IV. Appendix

a. Appendix A: Daily Journal

Week 1

August 10, 2020

- Office Orientation
- Packaged mailing kits
- Discussed potential project ideas

August 11, 2020

- Zoom Staff Meeting
- Discussed potential project ideas
- Researched outcome measures utilized in **PRECISION**
- Looked over **IRB** documentation

August 12, 2020

- In office training for Redcap Cloud and Greenphire
- Packaged mailing kits
- Took saliva samples to lab
- Plan date of first committee meeting
- Picked up keys for office
- Looked over ethics presentation and UNTHSC library biomedical literature review

August 13, 2020

- 10 am Zoom Staff Meeting
- Narrowing project ideas
- Discussed COVID changes to **PRECISION** with Ms. Johnson
- Reviewed previous **PRECISION** projects

August 14, 2020

- 8 am Zoom Study Task Training with Ms. Johnson
- 10 am Zoom meeting with Ms. Kearns
- Reviewed literature for questionnaire subjects **PSQ, RMQ**

- Discussed power analysis for possible project involving pain sensitivity

Cathleen M. Kearns

9-16-20

Site Mentor Signature

Date

Week 2

August 17, 2020

- 8 am Zoom Study Task Training with Ms. Johnson
- Finalize first committee meeting date
- Called 6 subjects for survey completion
- Literature review for pain sensitivity
- Work on research project proposal presentation

August 18, 2020

- 10 am Staff Zoom Meeting
- Work on research project proposal presentation
- Discussed possible extra data points of PSQ with Ms. Kearns

August 19, 2020

- In office training
- Assembled mailing packages
- Took saliva samples to lab
- Worked on presentation for committee meeting

August 20, 2020

- 10 am Staff Zoom Meeting
- Work on research project proposal presentation
- Phone conversation with Ms. Kearns about project

August 21, 2020

- Revised first committee meeting presentation with input from Ms. Kearns and Dr. Sumien

Cathleen M. Kearns

9-16-20

Site Mentor Signature

Date

Week 3

August 24, 2020

- Phone conversation with Ms. Kearns to discuss Zoom outage
- Presentation for First Committee Meeting
- Phone calls with 7 subjects

August 25, 2020

- Worked through voicemail backlog
- 10 am Zoom Staff Meeting
- Updated 9 subjects contact information
- Phone conversation with Ms. Johnson
- Phone calls with 6 subjects

August 26, 2020

- In office training
- Prepared mailing packages
- Took saliva samples to lab
- Enrolled subjects
- Phone call with 7 subjects for survey completion / reminders
- 3 pm Zoom with Ms. Kearns to discuss IRB and IRB changes

August 27, 2020

- 10 am Zoom Staff Meeting
- Phone conversation with Ms. Johnson
- Updated 3 subject contact information
- Compensated 8 subjects for survey completion
- Enrolled 8 subjects

August 28, 2020

- Phone calls with 3 subjects
- Enrolled subjects

August 31, 2020

- Out of Office for Medical School Interview

Cathleen M. Kearns

9-16-20

Site Mentor Signature

Date

Week 4

Sep 1, 2020

- Mailed outgoing packets
- Enrolled Subjects
- 10 am Zoom Staff Meeting

Sep 2, 2020

- Enrolled 4 subjects
- Took saliva samples to lab
- Assembled mailing packages
- Compensated subjects for completing surveys
- Called 3 subjects

Sep 3

- 10 am Zoom Meeting
- Phone call with Ms. Kearns about compensation issue
- Phone call with 4 subjects

Sep 4

- Phone call with Ms. Johnson
- Phone call with 3 subjects

Cathleen M. Kearns

9-16-20

Site Mentor Signature

Date

Week 5

Sep 8

- Called help desk to fix Outlook issue
- 10 am Zoom Staff Meeting
- Compensated subjects for survey completion
- Phone calls with 9 subjects
- Worked on research proposal rough draft, sent to Dr. Sumien for review

Sep 9, 2020

- Phone calls with 4 subjects
- Compensated subjects
- Checked voicemail and verified subject contacted
- Took saliva samples to lab
- SPADE training with Ms. Johnson

Sep 10

- Enrolled 5 subjects
- 10 am Zoom Staff Meeting
- Phone calls
- Training on subject with expired screen, rescreening process
- Compensated subjects

Sep 11

- Checked voicemail
- Emailed subject about expired screen
- Spoke with upset subject on the phone, explained the enrollment and compensation process
- Compensated subjects
- Phone call with Ms. Johnson about emailing SPADE charts to subjects

Cathleen M. Kearns

11-16-20

Site Mentor Signature

Date

Week 6

Sep 14

- Practiced sending SPADE charts
- Compensated subjects
- Worked on research proposal rough draft
-

Sep 15

- Enrolled 7 subjects
- Compensated subjects
- 10 am Zoom Staff Meeting
- Issues with the ORC Server spreadsheet
- Worked on research proposal rough draft

Sept 16

- Assembled mailing kits
- Compensated subjects
- Worked on research proposal rough draft, sent to committee for review

Sep 18

- Compensated subjects
- Emailed 2 SPADE graphs
- Phone calls with 4 subjects
- Spoke with subject about replacing misplaced clincard
- Mailed saliva kits to subjects
- Checked voicemail
- Phone call with Ms. Johnson

Cathleen M. Kearns

11-16-20

Site Mentor Signature

Date

Week 7

Sep 21

- Discussed budgeting issues with Ms. Johnson
- Phone call with Ms. Kearns
- Phone calls with 4 subjects
- Compensated subjects
- Created spreadsheets for missed visits

Sep 22

- Turned off missed visit surveys
- Compensated subjects
- 10 am Zoom Staff Meeting
- Phone calls with 5 subjects
- Issues with REDCap software throughout day, focused on data entry tasks
- Worked on research proposal rough draft, resent to committee for review

Sep 24

- Submitted research proposal with updates
- Checked voicemail
- Phone call with Ms. Kearns
- 10 am Zoom Staff Meeting
- Called 4 subjects for survey completion
- Enrolled subjects, REDCap error with subject numbering caused issue for further control enrollments so focused on cases
- Enrolled 4 subjects
- Worked on research proposal rough draft, resent to the committee for review

Sep 25

- Enrolled 2 cases
- Phone calls with 5 subjects
- Phone call with Ms. Johnson
- Compensated 3 subjects
- Created missed visit report
- Checked voicemail
- Research proposal approved

Cathleen M. Kearns

11-16-20

Site Mentor Signature

Date

Week 8

Sep 28

- Discussed budgeting strategy with Ms. Johnson
- Compensated subjects
- Worked on research project by looking into IBM SPSS data analysis

Sep 29

- REDCap issue with control numbering fixed, enrolled further controls
- 10 am Zoom Staff Meeting
- Phone call with Ms. Johnson
-

Sep 30

- Compensated backlog of subjects
- Enrolled
- Phone call with Ms. Johnson
- Phone call with 3 subjects

- Handed off saliva samples to lab
- In office training regarding future **IRB** changes

Oct 1

- Checked voicemail
- Compensated subjects
- Called 9 subjects
- Zoom with Ms. Johnson to walk through DocuSign screening and consents
- Mailed 2 saliva kits to subjects

Oct 2

- Compensated subjects
- Phone call with 5 subjects
- Printed **IRB**, reviewed for relevant changes
- Looked at spreadsheets for missing compensation data entry

Cathleen M. Kearns

11-16-20

Site Mentor Signature

Date

Week 9

Oct 5

- Practiced DocuSign consent screenings sent to 14 subjects
- Compensated subjects
- Enrolled 2 subjects
- Created missed visit spreadsheet, updated calendar

Oct 6

- Zoom staff meeting
- Compensated subjects
- Worked on missed visits
- Phone calls with 5 subjects
- Discussed missing mailed saliva kit with Ms. Johnson
- Enrolled 4 subjects
- Worked on pending saliva kits
- Worked on pending DocuSign consents

Oct 7

- In office training
- Compensated subjects
- Enrolled subjects and prepared saliva kits for hand off
- Took saliva kits to lab

Oct 8

- Phone call with Ms. Johnson and subject emails not being received
- Enrolled 4 subjects
- Contacted screened subject about expired screening
- Phone call with 1 subject

Oct 9

- Out of office medical school interview

Cathleen M. Kearns

11-16-20

Site Mentor Signature

Date

Week 10

Oct 12

- Checked voicemail
- Created missed visit spreadsheet
- Compensated subjects
- Phone calls with 8 subjects
- Called subject about partial data entry
- Marked subject lost to follow up, turned off surveys and clincard payments

Oct 13

- Created consent screening and docuSign spreadsheets, updated calendar
- Phone call with Ms. Kearns
- Compensated subjects
- 10 am Zoom Staff Meeting
- Phone call with 2 subjects
- Clincards expiring soon for some subjects, discussed future replacement options with Ms. Johnson
- Zoom Meeting with Ms. Kearns to discuss IRB

Oct 14

- Enrolled subjects, prepared saliva samples for lab
- Handed off saliva samples to lab
- Compensated subjects
- In office training for DocuSign consents

Oct 15

- Compensated subjects
- Enrolled 4 subjects
- 10 am Zoom Staff Meeting

- Phone call with Ms. Kearns
- Phone call with 3 subjects

Oct 16

- Data entry for survey based on email, updated medication list email
- Compensated subjects
- Phone calls with 5 subjects
- DocuSign screening and consent sent out

Cathleen M. Kearns

11-16-20

Site Mentor Signature

Date

Week 11

Oct 19

- Phone call with Ms. Johnson
- Documented missed visits for 3 subjects exceeding month window
- Signed 5 DocuSign consent packets and prepared saliva kits to be mailed
- Compensated subjects
- Phone call with 3 subjects

Oct 20

- Signed 3 DocuSign consent packets and prepared saliva kits to be mailed
- 1 pm Zoom Staff Meeting
- Phone calls 3 subjects
- Compensated subjects
- Dropped off mailed kits with FedEx

Oct 21

- In office training with Ms. Johnson for completing subject consent packets in DocuSign
- Training for tasks related to Ms. Johnson taking time off
- Enrolled 4 subjects
- Handed off saliva samples to lab
- Compensated subjects
-

Oct 22

- 10 am Zoom Staff Meeting
- Enrolled 3 subjects
- Phone calls with 7 subjects
- Compensated subjects

- Zoom meeting with Ms. Kearns

Oct 23

- Phone calls 5 subjects
- Compensated subjects
- Checked ORC emails

Cathleen M. Kearns

11-16-20

Site Mentor Signature

Date

Week 12

Oct 26

- Phone call with Ms. Kearns
- Checked ORC emails
- Enrolled 2 subjects
- Phone calls with 2 subjects
- Compensated subjects
- Signed 4 DocuSign consent packets and prepared saliva kits to be mailed
- Dropped off mailed kits with FedEx

Oct 27

- 10 am Zoom Staff Meeting
- Signed 4 DocuSign consent packets and prepared saliva kits to be mailed
- Phone call with Ms. Kearns
- Compensated subjects
- Dropped off mailed kits with FedEx

Oct 28

- Phone call with Ms. Johnson
- Compensated subjects
- Signed 6 DocuSign consent packets and prepared saliva kits to be mailed
- Dropped off mailed kits with FedEx

Oct 29

- 10 am Zoom Staff Meeting
- Phone calls for 4 subjects
- Enrolled 3 subjects
- Compensated subjects
-

Oct 30

- Phone calls for 5 subjects

- Compensated subjects
- 1 pm Zoom meeting with Ms. Kearns

Cathleen M. Kearns

11-16-20

Site Mentor Signature

Date

Week 13

Nov 2

- Signed 4 DocuSign consent packets and prepared saliva kits to be mailed
- Phone call with 1 subject
- Compensated subjects
- Dropped off mailed kits with FedEx

Nov 3

- 10 am Zoom Staff Meeting
- Phone calls with 5 subjects
- Compensated subjects
- Discussed DocuSign procedure with Ms. Johnson

Nov 4

- Signed 1 DocuSign consent packet and prepared saliva kit to be mailed
- Handed off saliva samples to lab
- Phone calls with 3 subjects
- Subject 7 enrollments
- Dropped off mailed kits with FedEx
-

Nov 5

- out of office for medical school interview

Nov 6

- Signed 7 DocuSign consent packets and prepared saliva kits to be mailed
- Recorded missed visits
- Enrolled 10 subjects
- Dropped off mailed kits with FedEx

Cathleen M. Kearns

11-16-20

Site Mentor Signature

Date

Week 14

Nov 9

- out of office for medical interview

Nov 10

- 10 am Zoom Staff Meeting
- Signed 4 DocuSign consent packets and prepared saliva kits to be mailed
- Phone calls with 2 subjects
- Compensated subjects
- 1 pm Zoom meeting with Ms. Kearns to discuss data entry task
- Dropped off mailed kits at FedEx

Nov 11

- Phone call with Ms. Kearns
- Compensated subjects
- Handed off saliva samples to lab
- Signed 3 DocuSign consent packets and prepared saliva kits to be mailed
-

Nov 12

- 10 am Zoom Staff Meeting
- Signed 3 DocuSign consent packets and prepared saliva kits to be mailed
- Phone call with 6 subjects
- Compensated subjects
- Dropped off mailed kits with FedEx

Nov 13

- Signed 11 DocuSign consent packets and prepared saliva kits to be mailed
- Enrolled 3 subjects
- Phone calls with 10 subjects
- Compensated subjects
- 1 pm Zoom meeting with Ms. Kearns to discuss clinical research administrative tasks
- Dropped off mailed kits with Fedex

Cathleen M. Kearns

11-16-20

Site Mentor Signature

Date

Week 15

Nov 16

- Phone call with Ms. Johnson
- Signed 12 DocuSign consent forms and prepared saliva kits to be mailed

Nov 17

- Phone call with Ms. Kearns
- Phone calls with 5 subjects
- Compensated subjects
- 1 pm Zoom Staff Meeting
- Enrolled 8 subjects
- Issue with enrolled subject resolved

Nov 18

- Handed off saliva samples to lab
- Enrolled subjects
- Phone calls with 4 subjects

Nov 19

- Phone calls with 3 subjects
- Enrolled 3 subjects
- 1 pm Zoom Staff Meeting
- Dropped off saliva kits at FedEx

Nov 20

- out of office for interview

Cathleen M. Kearns

1-28-21

Site Mentor Signature

Date

Week 16

Nov 23

- In office work
- Compensated subjects
- Phone calls with 3 subjects

Nov 24

- Phone call with Ms. Kearns
- 10 am Zoom Staff Meeting
- Enrolled 2 subjects
- Worked on mailing saliva kits for 6 subjects for COVID closure backlog

Nov 25

- In office preparation for the holiday
- Enrolled 8 subjects
- Handed off saliva samples to lab
- Compensated subjects

Cathleen M. Kearns

1-28-21

Site Mentor Signature

Date

Week 17

Nov 30

- In office work on holiday backlog
- Enrolled 19 subjects
- Compensated subjects

Dec 1

- 10 am Zoom Staff Meeting
- Enrolled 5 subjects
- Phone call with 3 subjects

Dec 2

- Compensated subjects
- Enrolled 10 subjects
- Handed off saliva samples to lab
- Prepared saliva mailing kits
- Phone calls with 9 subjects

Dec 3

- 10 am Zoom Staff Meeting
- Compensated subjects
- Ran report for upcoming missed visits
- Phone call with 3 subjects

Dec 4

- Compensated subjects
- Discussion with Ms. Kearns about compensation strategy for next few days with Greenphire

Cathleen M. Kearns

1-28-21

Site Mentor Signature

Date

Week 18

Dec 7

- Phone call with 2 subjects
- Verified screening subjects have been sent DocuSign consent packet
- Enrolled 5 subjects
- Compensated subjects

Dec 8

- 10 am Zoom meeting
- Responded to ORC emails
- Compensated subjects

Dec 9

- Phone call with 2 subjects
- Compensated subjects
- Answered voicemail calls
- Handed over saliva kits to lab

Dec 10

- Phone call with 3 subjects
- 11 am Zoom Staff Meeting
- Compensated subjects

Dec 11

- Phone call with 3 subjects
- Enrolled 2 subjects
- Assigned replacement ClinCard
- Compensated subjects

Cathleen M. Kearns

1-28-21

Site Mentor Signature

Date

Week 19

Dec 14

- Phone call with Ms. Johnson
- Answered voicemail calls
- Phone call with Ms. Kearns

- Responded to ORC emails
- Phone call with 2 subjects
- Signed 8 consent packets and mailed saliva kits
- Enrolled 10 subjects
- Learning new REDCap edition

Dec 15

- 10 am Zoom Staff Meeting
- Responded to ORC emails
- Enrolled 1 subject
- Compensated subjects
- Signed 8 consent packets and mailed kits

Dec 16

- Phone call with Ms. Johnson
- Phone call with 7 subjects
- Responded to ORC emails
- Enrolled 5 subjects
- Arranged 3 ClinCard replacements
- Signed re-consent for 3 subjects to new V19 form
- Compensated subjects

Dec 17

- Phone call with Ms. Johnson
- Responded to ORC emails
- 11 am Zoom Staff Meeting
- Compensated subjects
- Signed 14 consent packets and mailed saliva kits
- 2 pm zoom meeting with Ms. Kearns

Dec 18

- Phone calls with 4 subjects
- Responded to ORC emails
- Signed 8 consent packets and mailed saliva kits
- Enrolled 4 subjects
- Issue with REDCap character limit on forms and resending survey invitation
- Compensated subjects

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1-28-21

Site Mentor Signature

Date

Week 20

Dec 21

- Phone call with Ms. Kearns
- Responded to ORC emails
- Phone calls with 3 subjects
- Compensated subjects

Dec 22

- Phone call with Ms. Johnson
- 10 am Zoom Staff Meeting
- Responded to ORC emails
- 2 pm Zoom meeting with Ms. Johnson
- Phone calls with 8 subjects
- Compensated subjects

Dec 23 – half day

- Worked on missed visits and calling subjects before holiday close
- Responded to ORC emails
- Enrolled 12 subjects
- Phone call with Ms. Kearns
- Compensated subjects
- Called 5 subjects for survey completion or reminder

Dec 24 – Jan 3rd

UNTHSC closed

Cathleen M. Kearns

1-28-21

Site Mentor Signature

Date

Week 21

Jan 4

- In office working on holiday backlog
- Compensated subjects
- Handed over saliva kits to lab
- Assembled saliva kits
- Signed and scanned 4 mailed re-consent forms
- Signed 8 DocuSign consent packets and mailed kits

Jan 5

- 1 pm Zoom Staff Meeting
- Signed 3 consent packets and mailed kits
- Responded to ORC emails
- Compensated subjects

Jan 6

- Compensated subjects
- Responded to ORC emails
- Handed over saliva kits to lab
- Assembled saliva kits
- Verified subjects passing screening received DocuSign consent form

Jan 7

- 10 am Zoom Staff Meeting
- Responded to ORC emails
- Discussed timeline of research project with Dr. Sumien
- Signed 2 DocuSign consent packets and mailed kits
- Compensated subjects

Jan 8

- Enrolled 5 subjects
- Responded to ORC emails
- Compensated subjects

Cathleen M. Kearns

1-28-21

Site Mentor Signature

Date

Week 22

Jan 11

- out of office for medical school interview

Jan 12

- Called 4 subjects for survey completion and re-consent reminder
- 2 pm Zoom Staff Meeting
- Enrolled 8 subjects
- Re-consented 5 subjects to V19 form
- Compensated subjects

Jan 13

- In office
- Handed off saliva samples to lab
- Prepared 30 saliva mailing kits
- Signed 2 mailed re consent forms and scanned them
- Prepared PO Box mailing kit
- Compensated subjects

Jan 14

- out of office for medical school interview

Jan 15

- Called 3 subjects for survey completion and re consent reminder
- Compensated subjects
- Responded to ORC emails
- Learned how to mass email and sent out re consent reminders
- Enrolled 5 subjects
- Re consented 5 subjects to V19 consent form in DocuSign

Cathleen M. Kearns

1-28-21

Site Mentor Signature

Date

Week 23

Jan 18

UNTHSC Closed

Jan 19

- Compensated subjects
- Listened to voicemail and responded to inquiries
- Responded to ORC emails
- 10 am Zoom Staff Meeting
- Re consented 11 subjects to V19 consent form in DocuSign
- Phone survey completion with 3 subjects

Jan 20

- Compensated subjects
- Enrolled 3 subjects
- Replied to study email
- Checked voicemail and responded to messages
- Spoke with subject having difficulty filling out consent packet
- Signed 7 consent packets for enrollment

- Packaged and mailed 7 saliva kits

-

Jan 21

- Compensated subjects
- 10 am Zoom Staff Meeting
- Verified subjects passing screening have been sent consent packets
- Reconsented 5 subjects to V19 consent form
- Signed 6 consent packets for enrollment
- Signed 10 reconsent forms to update subjects to V19
- Packaged and mailed 6 saliva kits

-

Jan 22

- Compensated subjects
- Responded to ORC emails
- Called 2 subjects to complete quarterly follow up survey over phone
- Phone calls and left voicemails for 6 subjects about the reconsent forms that were mailed to their house
- Compared DocuSign and screening attempts to verify passing screens had a consent packet

Cathleen M. Kearns

3-17-21

Site Mentor Signature

Date

Week 24

Jan 25

- Compensated subjects
- In office to catch up with consent forms
- Assembled saliva kits mailers
- Signed 7 consent packets for enrollment
- Signed 7 reconsent forms to update subjects to V19
- Packaged and mailed 3 saliva kits
- Phone call with 1 subject to complete quarterly survey
- Phone calls and left voicemails to 5 subjects regarding reconsent process and forms

Jan 26

- Compensated subjects
- Listened to voicemail and responded to inquiries
- 10 am Zoom Staff Meeting
- Phone calls and left voicemails to 5 subjects regarding reconsent process and forms
- Signed 3 consent packets for enrollment
- Signed 6 reconsent forms to update subjects to V19
- Packaged and mailed 3 saliva kits

Jan 27

- Compensated subjects
- Called 4 subjects by phone to complete quarterly follow up survey
- Sent out mass email about re-consent process and how to complete
- Compared DocuSign and screening attempts to verify passing screens had a consent packet
- Signed 1 consent packet for enrollment
- Signed 5 re-consent forms to update subjects to V19
- Packaged and mailed 1 saliva kit

Jan 28

- Compensated subjects
- Responded to ORC emails
- Phone call with Ms. Kearns to discuss research budgeting and account types
- Training on converting a mistaken digital consent form into a paper process
- Signed 3 consent packets for enrollment
- Packaged and mailed 3 saliva kits

Jan 29

- Compensated subjects
- Responded to ORC emails
- Phone calls and left voicemails to 5 subjects regarding re-consent process and forms
- Signed 9 consent packets for enrollment
- Packaged and mailed 8 saliva kits
- Signed 5 re-consent forms to update subjects to V19

Cathleen M. Kearns

3-17-21

Site Mentor Signature

Date

Week 25

Feb 1

- Compensated subjects
- Listened to voicemail and responded to inquiries
- Responded to ORC emails
- Phone calls and left voicemails to 5 subjects regarding re-consent process and forms
- Discussed replacement of expiring ClinCards with Ms. Kearns

Feb 2

- Compensated subjects
- Phone call with Ms. Kearns
- Signed 6 consent packets for enrollment

- Packaged and mailed 6 saliva kits
- Zoom staff meeting at 10:30
- Phone calls and left voicemails to 5 subjects regarding re-consent process and forms

Feb 3

- Compensated subjects
- Phone call with Ms. Johnson
- Prepared 2 saliva kits to be mailed to PO Box addresses
- Packaged and mailed 7 saliva kits
- Prepared ClinCard replacement to be mailed to subject

Feb 4

- Compensated subjects
- Phone call with Ms. Johnson about mixed enrollment error
- 10 am Zoom Staff Meeting
- Compared DocuSign and screening attempts to verify passing screens had a consent packet
- Signed 5 consent packets for enrollment
- Packaged and mailed 5 saliva kits

Feb 5

- Compensated subjects
- Responded to ORC emails
- Phone call with Ms. Kearns about enrollments of cases being paused
- Phone call with Ms. Johnson
- Signed 4 consent packets for enrollment
- Packaged and mailed 4 saliva kits

Week 26

Feb 8

- Compensated subjects
- Responded to ORC emails
- Phone call with Ms. Kearns to discuss enrollment process to avoid error and potential solutions for fixing. Discussed issuance funding for ClinCard
- Signed 6 consent packets for enrollments
- Signed 5 re-consent forms to update subjects to V19
- Packaged and mailed 6 saliva kits

Feb 9

- Compensated subjects
- Emailed Doodle poll to Research Committee to schedule defense date and time
- Phone call with Ms. Kearns to discuss research project scheduling
- 10 am Zoom Staff Meeting
- Signed 8 re-consent forms to update subjects to V19
- Signed 3 consent packets for enrollment
- Packaged and mailed 3 saliva kits

Feb 10

- Compensated subjects
- Phone call with Ms. Johnson
- Phone call with Ms. Kearns
- Compared DocuSign and screening attempts to verify passing screens had a consent packet
- Signed 4 consent packets for enrollment
- Packaged and mailed 4 saliva kits

Feb 11

- Compensated subjects
- 10 am Zoom Staff Meeting
- Phone call with Ms. Kearns
- Signed 16 re-consent forms to update subjects to V19
- Signed 2 consent packets for enrollment
- Packaged 2 saliva kits to be mailed
- Called subject about incomplete survey being reset, resent link over email

Feb 12

- Compensated subjects
- Responded to ORC emails
- Phone call with 1 subject to complete quarterly survey
- Signed 3 consent packets for enrollment
- Signed 10 re-consent forms to update subjects to V19
- Packaged 3 saliva kits to be mailed

Cathleen M. Kearns

3-17-21

Site Mentor Signature

Date

Week 27

February 15 – 19 UNTHSC closed due to inclement weather.

Cathleen M. Kearns

3-17-21

Site Mentor Signature

Date

Week 28

Feb 22

- Compensated subjects
- Responded to ORC emails
- Enrolled 2 subjects into the study

- Sent out a mass email regarding pending consent forms in DocuSign
- Packaged and mailed 2 saliva kits

Feb 23

- Compensated subjects
- 10 am Zoom Staff Meeting
- Signed 3 consent packets for enrollment
- Prepared 3 saliva kits to be mailed
- Phone call with 1 subject to complete quarterly survey

Feb 24

- Compensated subjects
- Responded to ORC emails
- Compared DocuSign and screening attempts to verify passing screens had a consent packet
- Enrolled 8 subjects into the study

Feb 25

- Compensated subjects
- 10 am Zoom Staff Meeting
- Phone call with Ms. Johnson
- Responded to ORC emails

Feb 26

- Compensated subjects
- Listened to voicemail and responded to inquiries
- Phone call with 2 subjects to complete quarterly surveys
- Signed 2 consent packets for enrollment
- Packaged and mailed 2 saliva kits

Cathleen M. Kearns

3-17-21

Site Mentor Signature

Date

Week 29

Mar 1

- Compensated subjects
- Responded to ORC emails
- Phone call with Ms. Kearns to discuss research administration and continuing IRB processes
- Signed 3 consent packets for enrollment
- Packaged and mailed 3 saliva kits

Mar 2

- Compensated subjects
- Phone call with Ms. Johnson
- Sent out mass email regarding survey follow ups and potential missed visits

- Attended the Goldstein Lecture on Zoom “What Mediates the Effect of Osteopathic Medicine? Patient-Centered Care vs. Osteopathic Manipulative Treatment” discussing PRECISION Registry results
- Phone call with 4 subjects to complete quarterly surveys and remind them about the re-consent forms to sign

Mar 3

- In office
- Compensated subjects
- Data collection and analysis meeting with Dr. Licciardone for research project
- Discussed rough draft of research project with Dr. Sumien
- Enrolled 5 subjects into the study

Mar 4

- Compensated subjects
- Phone call with Ms. Kearns to discuss scheduling of end of internship
- Signed 1 consent form for enrollment
- Packaged and mailed 1 saliva kit
- Compared DocuSign and screening attempts to verify passing screens had a consent packet
-

Mar 5

- Compensated subjects
- Responded to ORC emails
- Phone call with 2 subjects to complete quarterly survey and reminded of re-consent forms
- Discussed change of research defense time with Dr. Mathew and Dr. Sumien
- Afternoon data interpretation and thesis writing

Cathleen M. Kearns

3-17-21

Site Mentor Signature

Date

Week 30

Mar 8

- Compensated subjects
- Responded to ORC emails
- Compared DocuSign and screening attempts to verify passing screens had a consent packet
- Listened to voicemail and responded to inquiries

Mar 9

- 10 am Staff Meeting on Zoom
- Signed 1 consent form for enrollment
- Packaged and mailed 1 saliva kit
- Worked on research project in the afternoon, researched data analysis and data presentation

Mar 10

- In office
- Compensated subjects
- Rearranged offices to vacate space for Health Pavilion
- Enrolled 8 subjects
- Handed off saliva samples to lab
- Literature review for research project
- Discussed IRB continuing review process with Ms. Kearns and grant funding approval process brought up during stars meeting

Mar 11

- 10 am Staff Meeting on Zoom
- Signed 1 consent packet for enrollment
- Packaged and mailed 1 saliva kit
- Worked on research project in afternoon, literature review on smoking and analgesic effect

Mar 12

- Compensated subjects
- Responded to ORC emails
- Signed 3 consent forms for enrollment
- Packaged and mailed 3 saliva kits
- Worked on research project in the afternoon, wrote rough draft

Cathleen M. Kearns

3-17-21

Site Mentor Signature

Date