ABSTRACT

Cortez-Neavel, Geordi, Building Resilience with Heart Rate Variability Biofeedback (HRVB): A Randomized Controlled Trial of HRVB to Reduce Emotional Exhaustion/Burnout in Emergency Department and Intensive Care Unit Providers. Master of Science in Clinical Research Management, November, 2019, 89 pp., 12 figures, 14 tables, journal entries, references, # titles.

Purpose: The purpose of this study was to compare perceived emotional exhaustion (assessed through MBI, CD-RISC, PSS, and PHQ-2) between two subject cohorts who received interventions designed to reduce emotional exhaustion through utilization of a Heartrate-Variability Biofeedback device, its partner app, and paired technique. We sought to evaluate the effectiveness of HRVB as a means to reduce emotional exhaustion as experienced by emergency and trauma care providers in a single-site, hospital setting (ED and ICU).

Hypothesis: The daily use of the HeartMath® HRVB device, Inner Balance application, and Quick Coherence technique over a 4-week period decreases emotional exhaustion in emergency and critical care providers.

Design: Providers (RN, PA, NP, MD/DO) working in Baylor University Medical Center's emergency department and intensive-care units participated in a 10-week study, consisting of a 4-week randomized control trial followed by a transition week and additional 5-week study "crossover" extension.

Results and Conclusion: Without the sample size to achieve the desired power of this study, no statistically significant conclusions can be drawn at this time. As of the writing of this thesis, the study is still ongoing, and, thus, new participant data may be included as a result of their completion of the RCT portion.

BUILDING RESILIENCE WITH HEART RATE VARIABILITY BIOFEEDBACK (HRVB): A RANDOMIZED CONTROLLED TRIAL OF HRVB TO REDUCEEMOTIONAL EXHAUSTION/BURNOUT INEMERGENCY DEPARTMENT ANDINTENSIVE CARE UNIT PROVIDERS

INTERNSHIP PRACTICUM REPORT

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And last, but certainly not least, I want to express my deepest gratitude for the initiative and guidance provided by the Trauma Research team, and my CRC, Alissa Old Crow, in particular.

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GLOSSARY

BUMC…… Baylor University Medical Center

CRA……. Clinical Research Associate

CRC……..…… Clinical Research Coordinator

ED……...…… Emergency Department

EMR…….……..... Electronic Medical Record

HRVB…….…. Heart-Rate Variability Biofeedback

ICU……...……. Intensive Care Unit

PI…… Principle Investigator

RCT…….…… Randomized Control Trial

REDCap……..… Research Electronic Data Capture

CHAPTER 1

Summary/Introduction:

Heart Rate Variability Biofeedback (HRVB) by HeartMath® has been implemented in many national healthcare systems and hospitals to reduce burnout and increase staff retention including: Mayo Clinic, Cleveland Clinic, UCLA, Duke, Methodist Health System, Kaiser Permanente, and others. There are also roughly 200 published journal articles supporting the technology (see review below). However, rigorous randomized controlled trials are lacking, and none have focused on Emergency Departments and Intensive Care Units.

Thus, my study aimed to test the efficacy of HRVB to reduce burnout symptoms in a prospective, randomized waitlist-controlled crossover trial with 100 providers (physicians, physician assistants, nurse practitioners, nurses) from the Baylor University Medical Center emergency and critical care departments. Participating providers were randomized to a 4-week HRVB intervention or to a 4-week waiting-list control condition. The intervention included 10-20 minutes of daily practice with the HRVB device. Once the first 4 weeks concluded, participants in the first cohort followed up for assessment and entered the post-intervention/follow-up phase, while the remaining participants began their intervention phase. The primary endpoint that we measured was emotional exhaustion (measured with the Maslach Burnout Scale) and was assessed at baseline, post-intervention phase, and at a 4-week follow-up (after conclusion of week 9).

Problem/Hypothesis and Significance

Research Question**:** Does the daily use of the HeartMath® HRVB device, Inner Balance application, and Quick Coherence technique over a 4-week period decrease emotional exhaustion in emergency and critical care providers?

> **H_0**: Subjects show no statistically significant* change, or a statistically significant increase in measured emotional exhaustion as compared to controls.
>
> **H_1**: Subjects show a statistically significant* decrease in measured emotional exhaustion as compared to controls.
>
> *Statistically significant is defined using a p value as less than or equal to 0.05 and in reference to a medium-large effect size.

Primary Outcome: The primary end point for this study was emotional exhaustion measured by the psychometrically reliable and valid Maslach Burnout Index (MBI-HSS).[1]

Secondary Outcome(s): Secondary end points included change in heart rate variability at rest, resilience, perceived stress, and mood (see variables below).

Significance: Studies have shown that burnout and stress levels are associated with on-the-job errors.[2-4] If this intervention shows a decrease in burnout, providers and patients alike might benefit. Additionally, provider satisfaction and retention could result from a decrease in burnout and emotional exhaustion.

Background

Medical provider burnout is a prevalent and costly issue in healthcare systems across the United States. Studies show symptoms of burnout (emotional exhaustion, fatigue, and depersonalization) in emergency medicine (EM) and intensive care (ICU) providers (physicians, physician assistants, nurse practitioners, nurses) to be as high as 70% in intensive care and as high as 80% in emergency care.[5-13] Emotional exhaustion serves as the primary driver and indicator of burnout, with research suggesting its efficacy in predicting the degree of burnout among healthcare professionals[14,15] Symptoms of burnout have deleterious effects on health, including increased blood pressure, decreased sleep quality, and decreased cardiovascular health.[5,16] Further, burnout leads to staff turnover that ultimately costs hospitals millions of dollars each year[17-21] Fortunately, recent studies show success in utilizing biofeedback interventions to decrease high levels of stress by encouraging emotional self-regulation, thereby decreasing emotional exhaustion and burnout.[5,6,22-28]

For example, a recently developed intervention, aimed at decreasing emotional exhaustion and stress in physicians, utilized a heart rate variability biofeedback (HRVB) device to teach self-regulation of the autonomic nervous system and showed statistically significant decreases in stress levels over an 8-week period.[22] The HRVB device used in the study, the HeartMath® Inner Balance Bluetooth device, employs a photoplethysmography sensor (similar to a pulse oximeter worn on a finger or earlobe) to measure variability in R-R intervals. The HeartMath® app, which can be used with a laptop, tablet, or cell phone, displays a breathing pacer and quantifies a real-time heart rate variability score and pattern. Users practice paced breathing while focusing on a positive feeling or emotion (gratitude, appreciation, care) until they can maintain a balance in their respiratory sinus arrhythmia, as indicated by the color green.

While HeartMath® HRVB has been successfully rolled out in many healthcare systems around the country (Cleveland Clinic, Walter Reed Military Medical Center, Kaiser Permanente, Cedars-Sinai Medical Center, NASA, US Army, US Navy, Stanford University, and Scripps Center for Integrative Medicine), inferences of success have been largely based on anecdotal case reports and pre- post- studies with no adequate control condition. To our knowledge, there have not been any scientifically rigorous studies conducted with healthcare providers using HRVB in emergency and critical care settings. Therefore, the aim of this study was to recruit providers from the emergency and intensive care departments at BUMC to participate in a 10-week HRVB intervention to assess its efficacy in decreasing and preventing burnout while increasing resilience and job satisfaction.

CHAPTER 2

Research Design and Methodology

Design:

The proposed design is a randomized-control trial. The study aimed to enroll 100 providers from the emergency medicine (ED) and critical care (ICU) departments. Occurring over a 10-week period, cohort participation was dependent on 4-week stages and a week-long transition period in between interventions. The timeline is shown in Table 1.1. Providers who expressed interest in the study consented and completed a 15- to 20-minute baseline assessment, which measured subjects' then-current level of stress, resilience, and emotional exhaustion, before randomizing to the intervention or waiting-list conditions. The assessment schedule is shown in Table 1.2.

During their respective first 4 weeks, 50 ED and ICU providers (Cohort 1) underwent an intervention phase (outlined in Procedures below), while 50 ED and ICU providers (Cohort 2) remained waitlisted. After Cohort 1 completed the 4-week intervention phase, both cohorts repeated the assessments (Table 1.2), and the waitlisted participants then transitioned to the intervention phase. Meanwhile, Cohort 1 transitioned into the post-intervention phase. At week 10, all participants completed a final round of assessments.

Timelines:

Table 1.1 Participant Activity Timeline

	Cohort 1	**Cohort 2**
Week 0	Recruitment	Recruitment
Week 1	Informed Consent **Questionnaires** 30-Min Intro Session Start HRVB Daily Practice	Informed Consent **Questionnaires**
Week 2	HRVB Daily Practice 5-min Weekly Check-In	Waitlist-Control
Week 3	HRVB Daily Practice 5-min Weekly Check-In	Waitlist-Control
Week 4	HRVB Daily Practice 5-min Weekly Check-In	Waitlist-Control
Week 5	Finish HRVB Daily Practice 5-min Weekly Check-In **Questionnaires** HRVB Devices Returned, Sanitized	Waitlist-Control **Questionnaires**
Week 6		30-Min Intro Session Start HRVB Daily Practice
Week 7		HRVB Daily Practice 5-min Weekly Check-In
Week 8		HRVB Daily Practice 5-min Weekly Check-In
Week 9		HRVB Daily Practice 5-min Weekly Check-In
Week 10	**Questionnaires**	Finish HRVB Daily Practice 5-min Weekly Check-In **Questionnaires** HRVB Devices Returned, Sanitized

Table 1.2 Assessment Schedule, Cohorts 1 & 2

Measure	Baseline	Week 5	Week 10
Demographics	X		
Contact Info	X		
Workplace Questions	X	X	X
MBI-HSS	X	X	X
CD-RISC	X	X	X
PSS	X	X	X
PHQ-2	X	X	X

Data Collection: Data was collected using a questionnaire through REDCap (a HIPAA compliant data capturing service), administered via electronic device with internet access and consisting of the four following components (in addition to demographic and workplace questionnaires utilized to contextualize the data):

Maslach Burnout index: Human Services Survey for Medical Personnel (MBI-HSS):

Maslach Burnout Index (MBI) assesses burnout in health care providers and consists of a 22-item, self-report questionnaire that addresses three scales: emotional exhaustion (EE), depersonalization (DP), and personal accomplishment (PA). The questionnaire takes approximately 10-15 minutes to complete, with EE consisting of 9 items, DP consisting of 5 items, and PA consisting of 8 Items. The score for each item uses a 7-level frequency scale, ranging from 0-6, with responses varying from "Never" (0) to "Daily" (6). The score totals for each item are then added up to provide a value for each scale. For EE, the ranges are as follows: 27+ (High), 17-26 (Moderate), 0-16 (Low). For DP, the ranges are as follows: 13+ (High), 7-12 (Moderate), 0-6 (Low). For PA, the ranges are as follows: 39+ (High), 32-38 (Moderate), 0-31 (Low). Internal consistency was estimated by Cronbach's coefficient α, which yielded reliability coefficients of 0.83 (frequency) and 0.84 (intensity) for the 25-item

scale. The reliability coefficients for the subscales were 0.89 (frequency) and 0.86 (intensity) for Emotional Exhaustion, 0.74 (frequency) and 0.74 (intensity) for Personal Accomplishment, and 0.77 (frequency) and 0.72 (intensity) for Depersonalization. Convergent Validity was demonstrated across 3 correlative sets at the time of development, and all three sets displayed significant evidence for MBI's validity.[1]

***The Connor-Davidson Resilience Scale (CD-RISC)*:**

The Connor-Davidson Resilience Scale short form is a widely used, self-report 10-item scale, that can be completed in approximately 10-15 minutes. The 10-item scale is derived from the larger 25-item scale and is designed to measure resilience when encountering diversity. The short form utilizes items 1, 4, 6, 7, 8, 11, 14, 16, 17, 19 from the original scale, and was developed by Drs. Campbell-Sills and Stein, at the University of California, San Diego, on the basis of factor analysis. The questionnaire uses 5-level frequency response categories (0 to 4), which range from "Not true at all" (0) to "True nearly all the time" (4). The scale has been developed using a total score of 40 for the 10-item questionnaire and tested as (i) a measure of degree of resilience, (ii) as a predictor of outcome to treatment with medication or psychotherapy, stress management and resilience-building; (iii) as a marker of progress during treatment; (iv) as a marker of biological (i.e. physical) changes in the brain. The scale also has promise as a method to screen people for high, intermediate or low resilience. The authors reported that the scale has high internal consistency (with a Cronbach's coefficient α for the full scale at 0.89), good test-retest reliability (with an intraclass correlation coefficient of 0.87), and adequate convergent and discriminant validity.[29]

Perceived Stress Scale (PSS):

The Perceived Stress Scale (PSS) utilizes a reliable and validated 10-item self-report questionnaire that assesses stress over the previous month. The questionnaire is designed to take approximately 5-10 minutes to complete. Items are rated from 0 (never) to 4 (all the time). PSS scores are obtained by reversing responses (e.g., 0 = 4, 1 = 3, 2 = 2, 3 = 1 & 4 = 0) to the four positively stated items (items 4, 5, 7, & 8) and then summing across all scale items. A short 4 item scale can also be made from questions 2, 4, 5 and 10 of the PSS 10 item scale. Scoring ranges of the PSS is as follows: 27-40 (High), 14-26 (Moderate), and 0-13 (Low). High PSS scores are associated with beliefs that the world is unpredictable and uncontrollable with external demands that exceed coping ability. The PSS proves to have adequate internal and test-retest reliability with Cronbach's coefficient α reporting at .86 and .85, respectively, which is correlated with ranges of self-report and behavioral criteria.[30]

Patient Health Questionnaire-2. (PHQ-2):

The Patient Health Questionnaire-2 is a 2-item self-report questionnaire that is used to inquire about the frequency of depressed mood and anhedonia over the past two weeks. The purpose of the PHQ-2 is not to establish final a diagnosis or to monitor depression severity, but rather to screen for depression in a "first step" approach. The PHQ-2 is derived from the full PHQ-9 and is designed to be completed in approximately 5 minutes. Patients who screen positive should be further evaluated with the PHQ-9 to determine whether they meet criteria for a depressive disorder. A PHQ-2 score ranges from 0-6. The authors identified a score of 3 as the optimal cut-off point when using the PHQ-2 to screen for depression. If the score is 3 or greater, major depressive disorder is likely. While studies show the PHQ-2

reports adequate reliability and validity, with high variability, the PHQ-9 reports high reliability, with Cronbach's α consistently over .84 for both internal and test-retest reliability and excellent construct validity.[31,32]

Methods and Tools:

Intervention: The study was carried out utilizing an HRVB Bluetooth device, the HeartMath® Inner Balance Bluetooth device, the HeartMath® paired, "Inner Balance" application, and the "Quick Coherence" technique.

Procedure:

Research associates recruited and consented potential participants on campus at BUMC at a time convenient to participants. A member of the research staff met potential participants in a private room on the BUMC campus to read the consent, answer questions, and give ample time for participant consideration prior to signing.

After the consent was signed, all participants were asked to complete study questionnaires via a secure REDCap (Research Electronic Data Capture) survey-link sent by study staff. After study measures were completed by the participant, study staff opened the randomization envelope and notified the participant of their cohort assignment. The PI, who had no prior contact with the participants, populated the envelopes with the assigned cohorts. The PI determined assignment order by using a random number generator.

Cohort 1 was then scheduled to attend an on-campus 30-minute introduction to the device at their earliest convenience. Cohort 2, meanwhile, served as the control for the first 4 weeks and will be contacted to come in for the 30-minute introduction to the device at week 5.

For Cohort 1, participants attended an approximately 30-minute session during which study staff demonstrated how to use the HRVB device, HeartMath's Inner Balance application, and the Quick Coherence technique. The introductory session occurred in a room on campus at a time convenient to participants. To accommodate varied schedules, multiple sessions of the introductory session were made available. One-on-one session were made available if necessary due to scheduling constraints.

During the 30-minute introductory session, participants were given the HRVB device to take home and were asked to practice daily for 10-20 minutes over the 4-week intervention period. Daily use of the HRVB device, as well as the resulting data generated by use, was tracked via HeartMath's HeartCloud, which only study staff and the individual user were able to access. Participants were also contacted by study staff weekly during the 4-week intervention via preferred method (phone, text, or email) to be sure they were on track with their daily practice and to have any questions answered.

After the conclusion of the first 4-week intervention phase (Week 5), Cohorts 1 & 2 were asked to fill out a second series of questionnaires, and Cohort 1 scheduled returns of the HRVB devices. A secure link containing study questionnaires was sent via secure electronic mail using REDCap, and the returned devices were sanitized. Cohort 1 was then encouraged to practice the breathing and emotional techniques as needed for the remaining 4 weeks of the study.

In the following weeks (Week 6), Cohort 2 will begin the same series of study activities. They will attend a 30-minute session where study staff will demonstrate how to use the HRVB device, HeartMath's Inner Balance application, and the Quick Coherence technique. The session will occur on campus at a time convenient to participants. To accommodate varied schedules, multiple sessions of the 30-miniute introductory session will be made available, and one-on-one sessions will be provided if necessary due to scheduling constraints.

During the 30-minute introductory session, participants in Cohort 2 will be given the HRVB device to take home and will be asked to practice daily for 10-20 minutes over the 4-week intervention period. Daily use of the HRVB device will be tracked via HeartMath cloud access that only study staff will be able to access. Participants will be contacted by study staff weekly during the 4-week intervention via preferred method (phone, text, or email) to be sure they are on track with their daily practice and to have any questions answered.

After the 4-week intervention with Cohort 2 is complete, participants in Cohorts 1 & 2 will be asked to complete their final post-assessment questionnaires via survey-link at a time convenient to them. The assessments will take approximately 15-20 minutes. Study staff will collect HRVB devices from Cohort 2 at this time.

Potential Risks:

i. Physical Risks: No physical risks due to participating in this study have been identified
ii. Psychological Risks: Some participants may experience some mild emotional discomfort, as some of the questions in the survey ask sensitive questions about anxiety and current mood state (i.e., burnout, anxiety, etc.).
iii. Social Risks: While study staff will take every precaution to protect participants' confidentiality, it is possible that participants' coworkers will know about their involvement in the study due to the group introductory sessions.
iv. Legal Risks: No legal risks due to participating in this study have been identified.
v. Economic Risks: No economic risks due to participating in this study have been identified.

Potential Benefits: Participants may experience a reduction in stress, anxiety, and burnout. Societal benefits include the knowledge gained from this study to determine the efficacy of HRV biofeedback at enhancing resilience and decreasing burnout in providers.

i. Potential future benefits to individuals with the condition being studied: It is hoped that results of this study will lead to the development and implementation of interventions to improve psychological outcome providers in the emergency department (ED) and intensive care unit (ICU), in addition to improving the quality of care given by providers working at BUMC.
ii. Potential benefits to society in general: Given the overall burden on society of caregiving for patients that have experienced trauma (healthcare expenses, lost wages, etc.), it is hoped that this study will lead to improved understanding of factors leading to reduced performance by providers and develop interventions to improve quality of care and functioning that providers can deliver to patients in the ED and ICU.

Sample Participants: The Trauma Research staff will recruit 100 BUMC ED and ICU providers (physicians (MD/DO), physician assistants (PA), nurse practitioners (NP), and nurses (RN) to participate in the 10-week study. Recruitment will occur via study flyer posted in common employee areas of the ICU and ED as well as a brief presentation given by study staff at morning huddles.

Subject Definition and Inclusion/Exclusion Criteria: Health care providers working in the ICU (4 Truett) or ED; this includes RN, PA, NP, and MD/DO.

i. Inclusion Criteria
    1. Adults aged 18-99
    2. Physicians, physician assistants, nurse practitioners, and nurses working in the emergency department, 4 Truett, 4 Roberts, or 7 Roberts
    3. Willing to provide contact information for follow-up assessments
    4. Willing to attend a 30-minute device set-up/introductory presentation and fill out approximately 15-20 minutes of questionnaires
    5. Willing to be contacted weekly for brief check-ins

ii. Exclusion Criteria
    1. Does not speak English fluently
    2. Does not have access to smart phone, laptop, or tablet
    3. Does not have unobstructed earlobe (eg; earrings that cannot be removed, perforated earlobe exceeding 1.2mm in diameter)

Informed Consent: Participants were consented at BUMC by trained study staff at a time convenient to study participants. Consent was obtained in a private room, and potential participants were encouraged to take ample time to review the consent prior to signing. Potential participants were informed of the aim of the project, what they would be asked to do as participants of the study and were encouraged to ask any questions they might have. Potential participants were told that participation is entirely voluntary as well as the risks and benefits of participation. If a participant discontinues work within the designated areas over the course of

the study or withdraws from the study, participant data obtained to that point may be used for analysis unless participant requests that data be withdrawn.

Sample Databases: Enrollment in this study was confidential and only known to fellow instructional session attendees and study staff. All participants will be assigned a study ID, and all measures were coded only with this number. Two REDCap databases (a secure, web-based software platform designed to support data capture for research studies) were created, and questionnaires were administered via secure survey-link.[33,34] One contains study measures (see Table 1.2 for list of assessments) for each participant, which were de-identified. The second was created to manage the demographic, contact, and scheduling variables. Only key study personnel have access to the databases. Consent documents are maintained in a locked file cabinet within a locked office in the Trauma Research Department.

CHAPTER 3

Results

DISCLAIMER: Results found in this section are not final and subject to change at any time in the near future. As of the writing of this thesis, the study is still ongoing, and, thus, new participant data may be included as a result of their completion of the Randomized Controlled Trial (RCT) portion. Additionally, an explanation of the insufficient data points can be found in the "Limitations" section below.

At the time of my defense, we are projected to have four participants with complete data for the RCT phase of this study: two participants from Cohort 1 and two participants from Cohort 2. For the Purposes of this thesis, no participants have completed the intervention portion within the RCT phase.

Initial baseline measurements for the first 19 participants have been provided below. At baseline, the MBI total score averaged 53.42±14.14 (Table 2.1), suggesting a moderate-to-high level of burnout in participants who completed questionnaires.

Table 2.1 – C1 + C2 Maslach Burnout Index Total Score

Total Count (N)	Missing	Unique	Min	Max	Mean	StDev	Sum	Percentile						
								0.05	0.10	0.25	0.50 Median	0.75	0.90	0.95
19	0 (0.0%)	15	26.00	78.00	53.42	14.14	1,015.00	35.00	36.80	42.50	55.00	63.50	69.00	77.10

Lowest values: 26, 36, 37, 41, 41
Highest values: 66, 67, 67, 77, 78

Further comparison of data between Cohort 1 and Cohort 2 shows roughly similar MBI scores, reporting a difference of only 4.17 between cohort means and 3.5 between cohort medians. While no conclusions can be definitively drawn between cohorts, as of yet, preliminary data suggests they experience similar levels of burnout.

Table 2.2 – C1 Maslach Burnout Index Total Score:

Total Count (N)	Missing	Unique	Min	Max	Mean	StDev	Sum	Percentile						
								0.05	0.10	0.25	0.50 Median	0.75	0.90	0.95
10	0 (0.0%)	10	26.00	77.00	51.40	15.03	514.00	30.95	35.90	41.75	52.50	59.75	68.00	72.50

Lowest values: 26, 37, 41, 44, 51
Highest values: 54, 56, 61, 67, 77

Table 2.3 – C2 Maslach Burnout Index Total Score:

Total Count (N)	Missing	Unique	Min	Max	Mean	StDev	Sum	Percentile						
								0.05	0.10	0.25	0.50 Median	0.75	0.90	0.95
9	0 (0.0%)	9	36.00	78.00	55.67	13.59	501.00	38.00	40.00	44.00	56.00	66.00	69.20	73.60

Lowest values: 36, 41, 44, 55, 56
Highest values: 56, 58, 66, 67, 78

Moving onto secondary measures, PSS scores report a mean of 15.32 and a median of 14 when observing both cohorts, together. When separated, Cohort 1 reports a difference in means of 0.39 and difference of 2.00 between medians. Both cohorts report similar scores and average well under a score of 31, suggesting low levels of perceived stress.

Table 3.1 – C1 + C2 Perceived Stress Scale Total Score:

Total Count (N)	Missing	Unique	Min	Max	Mean	StDev	Sum	Percentile						
								0.05	0.10	0.25	0.50 Median	0.75	0.90	0.95
19	0 (0.0%)	14	4.00	28.00	15.32	5.96	291.00	8.50	9.80	11.00	14.00	19.50	22.40	24.40

Lowest values: 4, 9, 10, 11, 11
Highest values: 21, 22, 22, 24, 28

Table 3.2 – C1 Perceived Stress Scale Total Score:

Total Count (N)	Missing	Unique	Min	Max	Mean	StDev	Sum	Percentile						
								0.05	0.10	0.25	0.50 Median	0.75	0.90	0.95
10	0 (0.0%)	7	10.00	22.00	15.50	4.30	155.00	10.45	10.90	11.75	15.00	17.75	22.00	22.00

Lowest values: 10, 11, 11, 14, 15
Highest values: 15, 17, 18, 22, 22

Table 3.3 – C2 Perceived Stress Scale Total Score:

Total Count (N)	Missing	Unique	Min	Max	Mean	StDev	Sum	Percentile						
								0.05	0.10	0.25	0.50 Median	0.75	0.90	0.95
9	0 (0.0%)	9	4.00	28.00	15.11	7.69	136.00	6.00	8.00	11.00	13.00	21.00	24.80	26.40

Lowest values: 4, 9, 11, 12, 13
Highest values: 13, 14, 21, 24, 28

CD-RISC scores also present similar values when comparing groups, with means of 30.79 (all participants), 30.60 (Cohort 1), and 31.00 (Cohort 2); medians report at 30, 30.50, and 29, respectively. Low averages suggest low levels of resilience in the target study population, further lending credit to the need for interventions to improve provider resilience.

Table 4.1 – C1 + C2 CD-RISC Total Score:

Total Count (N)	Missing	Unique	Min	Max	Mean	StDev	Sum	Percentile						
								0.05	0.10	0.25	0.50 Median	0.75	0.90	0.95
19	0 (0.0%)	14	17.00	40.00	30.79	6.28	585.00	20.60	24.20	27.50	30.00	37.00	38.00	38.20

Lowest values: 17, 21, 25, 26, 27
Highest values: 37, 38, 38, 38, 40

Table 4.2 – C1 CD-RISC Total Score:

Total Count (N)	Missing	Unique	Min	Max	Mean	StDev	Sum	Percentile						
								0.05	0.10	0.25	0.50 Median	0.75	0.90	0.95
10	0 (0.0%)	8	17.00	38.00	30.60	6.57	306.00	21.05	25.10	27.50	30.50	36.50	38.00	38.00

Lowest values: 17, 26, 27, 29, 30
Highest values: 31, 32, 38, 38, 38

Table 4.3 – C2 CD-RISC Total Score:

Total Count (N)	Missing	Unique	Min	Max	Mean	StDev	Sum	Percentile						
								0.05	0.10	0.25	0.50 Median	0.75	0.90	0.95
9	0 (0.0%)	7	21.00	40.00	31.00	6.32	279.00	22.60	24.20	28.00	29.00	37.00	37.60	38.80

Lowest values: 21, 25, 28, 28, 29
Highest values: 29, 34, 37, 37, 40

A brief look at PHQ2 scores suggests no further need for depression screening in the target population, as the medians all sit at 0, with quartile ranges suggests only a small number of individuals reporting higher than the median.

Table 5.1 – C1 + C2 Patient Health Questionnaire – 2 Total score:

Total Count (N)	Missing	Unique	Min	Max	Mean	StDev	Sum	Percentile						
								0.05	0.10	0.25	0.50 Median	0.75	0.90	0.95
19	0 (0.0%)	3	0.00	2.00	0.53	0.77	10.00	0.00	0.00	0.00	0.00	1.00	2.00	2.00

Lowest values: 0, 0, 0, 0, 0
Highest values: 1, 1, 2, 2, 2

Table 5.2 – C1 Patient Health Questionnaire – 2 Total score:

Total Count (N)	Missing	Unique	Min	Max	Mean	StDev	Sum	Percentile						
								0.05	0.10	0.25	0.50 Median	0.75	0.90	0.95
10	0 (0.0%)	3	0.00	2.00	0.70	0.95	7.00	0.00	0.00	0.00	0.00	1.75	2.00	2.00

Lowest values: 0, 0, 0, 0, 0
Highest values: 0, 1, 2, 2, 2

Table 5.3 – C2 Patient Health Questionnaire Total score:

Total Count (N)	Missing	Unique	Min	Max	Mean	StDev	Sum	Percentile						
								0.05	0.10	0.25	0.50 Median	0.75	0.90	0.95
9	0 (0.0%)	2	0.00	1.00	0.33	0.50	3.00	0.00	0.00	0.00	0.00	1.00	1.00	1.00

Lowest values: 0, 0, 0, 0, 0
Highest values: 0, 0, 1, 1, 1

Next, we can look at 4 participants who have completed the first phase of the 10-week study in the following table. A lack of consistency both between and among groups suggests more data will be required to make any assumptions.

Table 6.1 – Compared Baseline and Crossover Results for Participants 1-4

Measure	Cohort 1 (Pre)	Cohort 1 (Post)	Cohort 2 (Pre)	Cohort 2 (Post)
MBI - EE	**HRVB – 1 = 25** **HRVB – 4 = 19**	**HRVB – 1 = 9** **HRVB – 4 = 27**	**HRVB – 2 = 41** **HRVB – 3 = 19**	**HRVB – 2 = 22** **HRVB – 3 = 11**
MBI – DP	**HRVB – 1 = 8** **HRVB – 4 = 10**	**HRVB – 1 = 7** **HRVB – 4 = 12**	**HRVB – 2 = 19** **HRVB – 3 = 10**	**HRVB – 2 = 15** **HRVB – 3 = 12**
MBI - PA	**HRVB – 1 = 11** **HRVB – 4 = 12**	**HRVB – 1 = 8** **HRVB – 4 = 19**	**HRVB – 2 = 18** **HRVB – 3 = 16**	**HRVB – 2 = 9** **HRVB – 3 = 12**
CDR	**HRVB – 1 = 32** **HRVB – 4 = 31**	**HRVB – 1 = 38** **HRVB – 4 = 40**	**HRVB – 2 = 28** **HRVB – 3 = 37**	**HRVB – 2 = 34** **HRVB – 3 = 33**
PSS	**HRVB – 1 = 15** **HRVB – 4 = 11**	**HRVB – 1 = 4** **HRVB – 4 = 7**	**HRVB – 2 = 28** **HRVB – 3 = 14**	**HRVB – 2 = 17** **HRVB – 3 = 8**
PHQ2	**HRVB – 1 = 0** **HRVB – 4 = 0**	**HRVB – 1 = 0** **HRVB – 4 = 0**	**HRVB – 2 = 1** **HRVB – 3 = 0**	**HRVB – 2 = 0** **HRVB – 3 = 0**

Discussion & Conclusions

Discussion/Limitations:

Upon achieving complete data of at least 80 participants, the means, standard deviations, medians, and interquartile ranges will be used to describe continuous variables; frequencies, percentages, and odds ratios with 95% confidence intervals will be used to describe categorical variables.

First, potential carryover effects using a paired t-test of baseline differences between the first and second phases of the trial based on the sequence (introductory session + HRVB then no treatment vs. no treatment then introductory session + HRVB) will be examined. For variables with significant carryover effects, only data from the first phase of the trial using mixed-effects linear models with time and time-by-treatment interaction included will be examined. For variables without evidence of carryover effects, mixed-effects linear models with treatment condition, sequence/order, time, and the interactions of treatment x time and treatment x sequence/order will be used.

Limitations for this study can be separated into two categories: ones that affected data quality and others that affected timely completion of the study within the bounds of this internship practicum. Focusing first on data quality, limitations include the reliability of the HeartMath® tool (particularly its algorithm for measuring HRV), participant adherence, participants who work as contractors for BUMC (and thus may not spend the entirety of their work day at BUMC), limited technological literacy, assessment frequency (given that we are only assessing at every 4 weeks), and complications that arose from coordinating between the 4 respective floors within BUMC.

Additionally, in terms of representation within multiple demographics, we are limited by those that comprise workers at BUMC, and so replicability/translatability to other sites may be impaired. We attempted to satisfy a representative distribution across gender, race, and occupational duties (among other attributes measured for in the demographic questionnaire); however, as we are convenience sampling, we will continue to keep our sample population data in mind. Other limitations that affected the completion timeline for this study, include (but are not limited to) initial participant enrollment, consists of the following: delays due to Surgical and Nursing Peer Reviews, IRB understaffing/communication delays (non-responsive; major timeline delays) and stipulations (mainly recruitment flyer, odd requests,), the simultaneous rollout of Epic EMR during initial study launch (major timeline delays), and limited personnel on project (over capacity).

Conclusions:

Without the sample size to achieve the desired power of this study, no statistically significant conclusions can be drawn at this time. However, preliminary analysis of our first participant's data shows no consistent positive correlation between reduced emotional exhaustion and use of the HeartMath® Biofeedback Device and paired Quick Coherence Technique; however, scores across all measures support the need for new interventions to improve provider resilience and reduce likelihood of burnout. All participants, as a whole, reported low levels of resiliency and moderate-to-high levels of burnout, despite also reporting low levels of perceived stress. Preliminary data thus suggests investigation that further investigation will be required to determine which methods prove most effective.

Further Exploration:

While still in its pilot stage, the results of this study may offer insight into policy change within intensive-care and emergency departments. However, ultimately rejecting the null hypothesis (assuming a large enough sample population to achieve statistical significance) could lead to potential further investigation. Ideal next steps would pursue exploratory models addressing a possible causal mechanism of action involved in intervention-facilitated reduction of stress and emotional exhaustion.

Particularly, utilization of the HeartMath Inner Balance Bluetooth Device opens opportunities to explore the accuracy of device heartrate variability measurement. Other options include separating and comparing the components of our intervention (namely: Device, Gamified App, and Paired Technique) against each other to see if any of the individual components (or certain combinations, thereof) show a greater effect when compared to the others. Additionally, possible future studies may look past individual components of our intervention and seek to understand any potential psychological or biological mechanisms of action that support data showed in earlier studies.

CHAPTER 4

Practicum Site Summary:

My internship practicum transpired under the mentorship of behavioral psychologists Drs. Mark B. Powers and Ann Marie Warren—the director and co-founder (respectively) of BUMC's Trauma Research Department, which is located within Baylor T. Boone Pickens Cancer Hospital. Dr. Ann Marie Warren founded the Trauma Research Department alongside Dr. Michael L. Foreman in 2011. Since then, the department has increased its grant funding by over $7 million and published an average of 20 presentations and 12 peer-reviewed articles, annually—numbers which only continue to grow.

BUMC, a part of Baylor Scott & White Health, serves as one of five Level-1 Trauma Centers in the Dallas/Fort Worth Area; it also serves as a major center for patient care as well as medical training and research for the North Texas area.

As a result of my provider-based research, I also had the opportunity to spend much of my time on three intensive-care unit floors (7 Roberts, 4 Roberts, and 4 Truett) in addition the BUMC's Emergency Department. My study investigating provider resilience serves as one of the first significant points of collaboration between the Trauma Research Department and the providers on respective patient floors.

Summary of Experiences:

Unlike other internship practicums, I spent the majority of my time at Baylor University Medical Center's Trauma Research Department constructing and organizing the study I intended to execute for the purposes of this program. I felt that I experienced a particularly thorough education in, not only study design, but in preparation for a logistically smooth and manageable rollout. I truly felt part of the Trauma Research team, attending weekly morning huddles, weekly team meetings, and even daily morning meditation.

My internship practicum began with writing and polishing the study protocol alongside my CRC. After refining our drafts and receiving edits from my PI and other research staff, we turned to our next goal of submitting to and receiving approval from both Surgical Peer Review (SPR) and Nursing Research Council (NRC) boards—a mandatory step considering the targeting of providers at BUMC. Both boards required my CRC and I craft proposals separate from our IRB applications, and then present at their respective meetings.

After gaining approval from both boards, we moved towards polishing our methods and materials based on stipulations and feedback we received. In total we constructed the following set of recruitment materials, instructional guides, and questionnaires (all of which can also be found in their respective appendices).

1. Recruitment Flyer
2. Pre-Shift Huddle Announcements
3. Introductory Device Presentation
4. Device Set-Up Manual
5. HeartCloud Set-Up Manual

Simultaneous to the construction of necessary participant-facing materials, we generated an extensive array of progress/oversight logs and checklists within REDCap and Microsoft Excel in order to facilitate a successful study.

Submission to the BUMC IRB (named iRIS) came after final rounds of edits. However, as previously stated in the discussion section of this report, the difficulty in resolving IRB roadblocks served as a major limitation that prevented timely completion of the full study. But after resolving all stipulations and settling miscommunications, we began our recruitment efforts immediately after moving into open-to-enrollment status.

Our initial strategies relied on two primary modes of contact with potential participants: recruitment flyers and huddle-pitches. Yet again, efforts to gain momentum were stalled by the rollout of Epic's electronic medical record system. After rounding on each floor, we understood that the stress that arrived with Epic had demotivated providers from reaching out to study staff.

After waiting for the lingering commotion of the new EMR system to pass, both the study CRC and I made intermittent attempts to count the number of tabs taken from recruitment flyers as a soft means of gauging provider interest. Our second tally yielded 67 tabs taken; however, we only received contact from a single provider. So we utilized nurse-researchers, found on the respective floors, to gather input as to why providers were hesitant to contact us. We ultimately found that providers were intimidated by the apparently high commitment of our study, due to additional elements that we were required to add to recruitment flyers under IRB stipulations.

Our current rollout of the study has since proven much more successful in our recruitment efforts. We are now utilizing nurses present on each floor to act as liaisons between potential participants and study staff, so as to alleviate any reservations about study demands.

APPENDICES

Appendix A:

Baylor IRB Approval Letter

IRB Approval – Expedited Review of New Study

To: Ann Marie Warren, PhD Copy

to: Ann Marie Warren, PhD, Geordi Cortez-Neavel, Mark Powers, PhD Date:

August 27, 2019

Re: 019-266

Building Resilience with Heart Rate Variability Biofeedback (HRVB): A Randomized Controlled Trial of HRVB to Reduce Burnout in Emergency Department and Intensive Care Unit Providers
Reference Number: 333287

Your new proposal was reviewed by a designated member of Baylor Scott & White Research IRB Red via expedited review.

This study was determined to be eligible for expedited review as it involves no greater than minimal risk to the subjects and fits into the following categories from the 1998 approved list:

Category 5: Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis)

Category 7: Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies

This review included the following components:

Submission Components
Form Name

Review Response Submission Form
Initial Review Submission Packet
Study Application - Review by BSWRI IRB

Study Document

Version Version 3.0 Version 1.1 Version 1.1

Outcome
Approved as Presented Approved as Presented Approved as Presented

Title
Appendix C
Appendix A
ED STS Flyer 2
Protocol
Nursing Research Council Approval Form Appendix B
SRPRC Form 18 and 34
PSS
phq2
CD-RISC

Study Consent Form
Title
HRVB Resilience Consent

Version # Version 1.1 Version 1.1 Version 1.2 Version 2.0 Version 1.0 Version 1.0 Version 1.0 Version 1.0 Version 1.0 Version 1.0

Version # Version 1.1

Version Date 07/10/2019 07/09/2019 07/09/2019 07/22/2019 07/15/2019 07/10/2019 07/09/2019 07/02/2019 07/02/2019 07/02/2019

Version Date 07/22/2019

Outcome Approved Approved Approved Approved Approved Approved Approved Approved Approved Approved

Outcome Approved

Your submission has been approved. The approval period begins on 08/27/2019 and expires on 08/26/2020. Your next continuing review is scheduled for 06/26/2020.

This study is approved to be conducted at the following locations:
Baylor University Medical Center, ED
Baylor University Medical Center, Roberts, BUMC-Roberts 7
Baylor University Medical Center, Truett, BUMC-Truett 4/ICU

Baylor University Medical Center, Roberts, BUMC-Roberts 4 North/ICU Baylor University Medical Center

The following individuals are approved as key study personnel or are acknowledged as study contacts/administrative support/department approvers:
AZIZ, MARIA, MD; Cortez-Neavel, Geordi; Foreman, Michael L., MS, MD, FACS; Old Crow, Alissa; Powers, Mark, PhD; Warren, Ann Marie, PhD

Informed consent must be obtained utilizing the document(s) as listed above. You must utilize a copy of the consent which includes the IRB approval stamp. Therefore, you will need to print new copies from the database which include the IRB approval stamp.

The recruitment plan has been evaluated for compliance with HIPAA. It has been determined to be compliant in part under the preparatory to research standards and additionally compliant due to the approval by the IRB/Privacy Board of a partial waiver of HIPAA authorization under 45 CFR 164.512(i)(2)(ii). These two determinations allow the recruitment strategy as outlined to be carried out. In the event you make changes to your recruitment strategy, additional review is required by the IRB/Privacy Board.

All events that occur on this study including protocol deviations, serious adverse events, unanticipated problems involving risks to subjects/others, subject complaints or other similar events must be reported to the IRB in accordance with the respective policies.

Remember that this study is approved to be conducted as presented. Any revisions to this

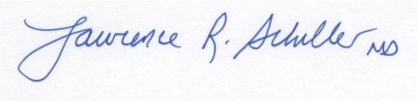
proposal and/or any of the referenced documents must be approved by the IRB prior to being implemented. Additionally, if you wish to begin using any new documents, these must receive IRB approval prior to implementation of them in the study.

IRB approval may not be the final approval needed to begin the study. All contractual, financial or other administrative issues must be resolved through Baylor Scott & White Research Institute prior to beginning your study.

For Investigator Initiated studies that meet the requirements to be posted on www.clinicaltrials.gov; as Principal Investigator, it is your responsibility to ensure that your study is listed prior to enrolling the first subject. Instructions on fulfilling this requirement can be found in iRIS under the “Help” tab.

If you need additional assistance, please contact the IRB Specialist at 214-820-9692 (NTX) 254-771-4869 (CTX).

Sincerely,



Signature applied by Lawrence R. Schiller on 08/27/2019 01:25:39 PM CDT

Appendix B:

Student Journal – Formatted as Weekly Reports

Weekly Update

Week: 6/03 – 6/07
Name: Geordi Cortez-Neavel
Title: Research Intern
Educational Status: BA, MS (Candidate)

Assigned Projects	Assigned Publications	Miscellaneous	Meetings
• ED STS	•	•	• Met with Alissa Old Crow, Dr. Aziz, and Dr. Powers on Tuesday (06/06) • Committee Meeting concerning internship practicum will occur on 6/11 with Dr. Powers and Dr. Warren.

Weekly Progress Updates:

- **Study 1**
    - Recruitment/Follow-ups
        - Screened: N/A
        - Eligible/Approached: N/A
        - Declined: N/A
        - Consented: N/A

- Screened: N/A
- Participants' in window: N/A
- Follow-up Interviews: N/A

Publications:

- N/a

Any Hiccups/Road Blocks That Need Dept. Assistance:

- Not this week

Action Items Dated :

S.No.	Action Item	Progress	Status of Action Item (Open/ Closed).
6/7/2019	Committee Meeting	Preparations in progress for committee meeting on 6/11	open
6/7/2019	Learning Modules	In-progress,	Open
6/7/2019	ED STS study protocol	Finalizing elements of the protocol. Planning to distribute for peer review next week.	Open
6/7/2019	Co-Facilitator Training	Purchase order generated, and coordinating date of training.	Open
6/5/2019	Gain IRIS approval	Account created and IRIS approval received	Closed
6/5/2019	Physician/Nurse Shadowing	After receiving reply from Karen, in the process of completing required forms	Open
6/5/2019	Generate Internal Audit Checklist	Begin completing internal audit checklist per Dr. Aziz's instructions, planning to complete 6/10	Open
	Generate GANT/Project Timeline with important dates and action items for team	Begun constructing timeline, planning to complete 6/10 or 6/11	Open

Weekly Update

Week: 6/10 – 6/14
Name: Geordi Cortez-Neavel
Title: Clinical Research Intern
Educational Status: BA

Assigned Projects	Assigned Publications	Miscellaneous	Meetings
• ED STS	• ED STS – Outcome • ED STS – Methods • ED STS – Review/Meta Analysis	•	• Committee Meeting • Weekly Huddle • Weekly Team Meeting •

IRB Study	Submission Type (CR, AE/SAE, etc.)	Submission Status	Outcome
ED STS	CR	Not Submitted	n/a

Weekly Progress Updates: (N/A)

- **Study One – N/A**
  - Recruitment/Follow-ups
    - Eligible/Approached:
    - Declined:
    - Consented/Interviewed:
    - Participants' emailed:
    - Follow-up Interviews:
- **Study One**
  - Recruitment/Follow-ups
    - Eligible/Approached:
    - Declined:
    - Consented/Interviewed:
    - Participants' emailed:
    - Follow-up Interviews:
- **See Action Items Below**

Publications: (N/A)

- **Paper One**
  - Not currently with me. See action items.

Any Hiccups/Road Blocks That Need Dept. Assistance:

- Not this week

Action Items Dated:

S.No.	Action Item	Progress	Status
1)	Committee Meeting	Committee meeting occurred on 6/11 at 10 am, and I was approved to move forward with the current study	Completed
2)	ED STS Study Protocol	Protocol completed, and surgical peer review template completed and submitted on 6/13	Completed
3)	Co-Facilitator Training	Purchase order generated via Alissa, and will be sent out once item # has been received	In Progress
4)	Physician/Nurse Shadowing	Conversed with Michelle Fresnedo on following during grand rounds, and meeting attendings. Currently filling out forms to return to Karen for shadowing.	In Progress
5)	GANNT Project Timeline	Timeline draft with important dates generated, and will review before disseminating to the rest of key personnel	In Progress

Personal Items Dated:

S.No.	Action Item	Progress	Status
1)	Consenting Shadowing	After discussing with Alissa, and realizing that no qualitative, subjective assessments must be done, I will be required to shadow for 20 hours before I am approved to consent research subjects	Ready to Initiate (In Progress)
2)	Begin writing consent form in anticipation of IRB Submission	After finalizing protocol, I have begun writing the consent form, using form 34 and consent templates found on IRIS site.	In Progress
3)	Complete Form 34	See above	In Progress
4)	Begin and Finish Nursing Research Group review form	Similarly to the surgical peer review form, I have begun filling out and completing the nursing research group review form for submission prior to IRB submission	In Progress
5)	Update IRB on IRIS	After finalizing research protocol, I will now review IRB submission template initiated by Alissa and include essential information and citations	In Progress
6)	Epic EMR Training	On Tuesday I will attend Epic EMR training with Dr. Maria Aziz, to familiarize myself with the program	In Progress

7)	RN Researcher Selection for ED STS	After conferring with Dr. Powers and Alissa, we must locate and select a suitable, qualified RN within one of the two research sites (ED or 4Truett ICU) before submitting to IRB	In Progress
8)			
9)			

Weekly Update

Week: 6/17 – 6/21
Name: Geordi Cortez-Neavel
Title: Clinical Research Intern
Educational Status: BA

Assigned Projects	Assigned Publications	Miscellaneous	Meetings
• ED STS	• ED STS – Outcome • ED STS – Methods • ED STS – Review/Meta Analysis	•	• Weekly Huddle • Weekly Team Meeting •

IRB Study	Submission Type (CR, AE/SAE, etc.)	Submission Status	Outcome
ED STS	CR	Not Submitted	n/a

Weekly Progress Updates: (N/A)

- **Study One – N/A**
  - Recruitment/Follow-ups
    - Eligible/Approached:
    - Declined:
    - Consented/Interviewed:
    - Participants' emailed:
    - Follow-up Interviews:
- **Study One**
  - Recruitment/Follow-ups
    - Eligible/Approached:
    - Declined:

    - Consented/Interviewed:
    - Participants' emailed:
    - Follow-up Interviews:
- **See Action Items Below**

Publications: (N/A)

- **Paper One**
    - Not currently with me. See action items.

Any Hiccups/Road Blocks That Need Dept. Assistance:

- Not this week

Action Items Dated:

S.No.	Action Item	Progress	Status
1)	Nursing Research Group Review Submission	Upon completing the surgical peer review submission, I have worked on completing the Nursing Research Group review form and have added to the HeartMath ED Sharepoint for further review by Alissa. We will then disseminate to other staff for final review before submission	In Progress
2)	ED STS Study Protocol	Protocol completed, and surgical peer review template completed and submitted on 6/13. Further edits were made as of 6/20 in order to update the measures surrounding language.	Completed
3)	Co-Facilitator Training	Purchase order generated via Alissa, and will be sent out once item # has been received	In Progress
4)	Physician/Nurse Shadowing	Conversed with Michelle Fresnedo on following during grand rounds, and meeting attendings. Currently filling out forms to return to Karen for shadowing. Will begin shadowing within the next 3 weeks.	In Progress
5)	GANNT Project Timeline	Timeline draft with important dates generated, and will review before disseminating to the rest of key personnel	In Progress

Personal Items Dated:

S.No.	Action Item	Progress	Status
1)	Consenting Shadowing	After discussing with Alissa, and realizing that no qualitative, subjective assessments must be done, I will be required to shadow for 20 hours before I am approved to consent research subjects. After Team meeting, we decided I will shadow for COTI and practice doing consenting with some mock OASIS interviews. This will begine while waiting for IRIS approval.	Ready to Initiate (In Progress)
2)	Begin writing consent form in anticipation of IRB Submission	After finalizing protocol, I have begun writing the consent form, using form 34 and consent templates found on IRIS site.	In Progress
3)	Complete Form 34	See above	In Progress
4)	Begin and Finish Nursing Research Group review form	Similarly to the surgical peer review form, I have begun filling out and completing the nursing research group review form for submission prior to IRB submission	In Progress
5)	Update IRB on IRIS	After finalizing research protocol, I will now review IRB submission template initiated by Alissa and include essential information and citations	In Progress
6)	RN Researcher Selection for ED STS	Selected Trenton Raff as our RN researcher. Additionally added 4R and 7R to the study based on his recommendation.	Complete
7)	Student Research Proposal	Submission of student research proposal for my CRM Practicum internship is due on July 10th. As this is the sole determinant of my summer semester grade, this will take up some time and serve as a significant priority.	In Progress

Weekly Update

Week: 6/24 – 6/28
Name: Geordi Cortez-Neavel
Title: Clinical Research Intern
Educational Status: BA

Assigned Projects	Assigned Publications	Miscellaneous	Meetings
• ED STS	• ED STS – Outcome • ED STS – Methods • ED STS – Review/Meta Analysis	•	• Weekly Huddle • Weekly Team Meeting • Committee Review of Research Proposal (due 07/10/19)

IRB Study	Submission Type (CR, AE/SAE, etc.)	Submission Status	Outcome
ED STS	CR	Not Submitted	n/a

Weekly Progress Updates: (N/A)

- **Study One – N/A**
  - Recruitment/Follow-ups
    - Eligible/Approached:
    - Declined:
    - Consented/Interviewed:
    - Participants' emailed:
    - Follow-up Interviews:
- **Study One**
  - Recruitment/Follow-ups
    - Eligible/Approached:
    - Declined:
    - Consented/Interviewed:
    - Participants' emailed:
    - Follow-up Interviews:
- **See Action Items Below**

Publications: (N/A)

- **Paper One**
  - Not currently with me. See action items.

Any Hiccups/Road Blocks That Need Dept. Assistance:

- Not this week

Action Items Dated:

S.No.	Action Item	Progress	Status
1)	Nursing Research Group Review Submission	Due to some delays in responses, NRG submission will likely get pushed to next week. However, it is in its final stages of edits and will likely be submitted on Monday or Tuesday.	In Progress
2)	ED STS Study Protocol	Protocol completed, and awaiting NRG submission review before compiling with rest of materials for IRIS submission.	Completed
3)	Co-Facilitator Training	Purchase order generated via Alissa, and will be sent out once item # has been received. Still no update as to when it will occur	In Progress
4)	Physician/Nurse Shadowing	Conversed with Michelle Fresnedo on following during grand rounds, and meeting attendings. Currently filling out forms to return to Karen for shadowing. Will begin shadowing within the next 3 weeks.	In Progress
5)	IRIS Submission	Awaiting final review of 2 documents before moving forward with IRIS submission. Expected to submit in the week of 07/08-07/12. After finalizing research protocol, I will now review IRB submission template initiated by Alissa and include essential information and citations	In progress
6)	Seeking Resident to add on to ED STS	After submitting to surgical peer review, a recommendation was given to add on a resident physician. Alissa and I are currently coordinating with Dr. Powers and Michelle to find an enthusiastic resident who will productively contribute to the study.	In progress
7)	Consent Form finalization	Consent form has been reviewed and will go through one round of full team review before finalizing it. Then forms will be compiled for submission for IRIS approval.	In Progress

Personal Items Dated:

S.No.	Action Item	Progress	Status
1)	Consenting Shadowing	After discussing with Alissa, and realizing that no qualitative, subjective assessments must be done, I will be required to shadow for 20 hours before I am approved to consent research subjects. After Team meeting, we decided I will shadow for COTI and practice doing consenting with some mock OASIS interviews. This will begin while waiting for IRIS approval.	Ready to Initiate (In Progress)
2)	Internship Practicum Research Proposal	Submission of student research proposal for my CRM Practicum internship is due on July 10th. As part of my Internship Practicum I will be required to submit a research proposal for ED STS to my committee. this is the sole determinant of my summer semester grade, this will take up some time and serve as a significant priority. I have completed my first draft and have sent it to my major advisor for initial review.	

Weekly Update

Week: 7/01 – 7/05
Name: Geordi Cortez-Neavel
Title: Clinical Research Intern
Educational Status: BA

Assigned Projects	Assigned Publications	Miscellaneous	Meetings
• ED STS	• ED STS – Outcome • ED STS – Methods • ED STS – Review/Meta Analysis	•	• Weekly Huddle • Weekly Team Meeting • Committee Review of Research Proposal (due 07/10/19)

IRB Study	Submission Type (CR, AE/SAE, etc.)	Submission Status	Outcome
ED STS	CR	Not Submitted	n/a

Weekly Progress Updates: (N/A)

- **Study One – N/A**
  - Recruitment/Follow-ups
    - Eligible/Approached:
    - Declined:
    - Consented/Interviewed:
    - Participants' emailed:
    - Follow-up Interviews:
- **Study One**
  - Recruitment/Follow-ups
    - Eligible/Approached:
    - Declined:
    - Consented/Interviewed:
    - Participants' emailed:
    - Follow-up Interviews:
- **See Action Items Below**

Publications: (N/A)

- **Paper One**
  - Not currently with me. See action items.

Any Hiccups/Road Blocks That Need Dept. Assistance:

- Need Dr. Powers to review the NRG Protocol Submission

Action Items Dated:

S.No.	Action Item	Progress	Status
1)	Nursing Research Group Review Submission	Still awaiting final review from Dr. Powers.	In Progress
2)	Co-Facilitator Training	Purchase order completed and waiting to schedule training	In Progress
4)	Physician/Nurse Shadowing	Conversed with Michelle Fresnedo on following during grand rounds, and meeting attendings. Currently filling out forms to return to Karen for shadowing. Will begin shadowing within the next 3 weeks.	In Progress
5)	IRIS Submission	Awaiting final review of 2 documents before moving forward with IRIS submission. Expected to submit in the week of 07/08-07/12. After finalizing research protocol, I will now review IRB submission template	In progress

		initiated by Alissa and include essential information and citations	
6)	Seeking Resident to add on to ED STS	After submitting to surgical peer review, a recommendation was given to add on a resident physician. Alissa and I are currently coordinating with Dr. Powers and Michelle to find an enthusiastic resident who will productively contribute to the study.	In progress
7)	Consent Form finalization	Consent form waiting for final review from PI	In Progress

Personal Items Dated:

S.No.	Action Item	Progress	Status
1)	Consenting Shadowing	After discussing with Alissa, and realizing that no qualitative, subjective assessments must be done, I will be required to shadow for 20 hours before I am approved to consent research subjects. I have begun shadowing COTI consenting process.	In Progress
2)	Internship Practicum Research Proposal	Meeting on 7/05 with Major Advisor at UNTHSC in Fort Worth, Texas. Currently circulated the proposal to all committee members.	In Progress
3)	Creating Templates for Appendices and navigating REDCap questionnaire generation	Alissa and I are working together to further elaborate on protocol.	In progress

Weekly Update

Week: 7/08 – 7/12
Name: Geordi Cortez-Neavel
Title: Clinical Research Intern
Educational Status: BA

Assigned Projects	Assigned Publications	Miscellaneous	Meetings
• ED STS	• ED STS – Outcome • ED STS – Methods • ED STS – Review/Meta Analysis	•	• Weekly Huddle • Weekly Team Meeting • Nursing Research Council Review of Protocol Submission (7/15)

IRB Study	Submission Type (CR, AE/SAE, etc.)	Submission Status	Outcome
ED STS	CR	Awaiting Submission (ready)	n/a

Weekly Progress Updates: (N/A)

- **Study One – N/A**
  - Recruitment/Follow-ups
    - Eligible/Approached:
    - Declined:
    - Consented/Interviewed:
    - Participants' emailed:
    - Follow-up Interviews:
- **Study One**
  - Recruitment/Follow-ups
    - Eligible/Approached:
    - Declined:
    - Consented/Interviewed:
    - Participants' emailed:
    - Follow-up Interviews:
- **See Action Items Below**

Publications: (N/A)

- **Paper One**
  - Not currently with me. See action items.

Any Hiccups/Road Blocks That Need Dept. Assistance:

- Not at this time

Action Items Dated:

S.No.	Action Item	Progress	Status
1)	Nursing Research Group Review Submission	Submitting to research council and awaiting presentation	Completed
2)	Co-Facilitator Training	Purchase order completed and waiting to schedule training. Will likely occur in the next 2-3 weeks.	In Progress
4)	Physician/Nurse Shadowing	Shadowing will begin after iRIS submission, likely the week of 7/15	In Progress
5)	iRIS Submission	iRIS application submitted then withdrawn, due to conflicting information on whether or not NRC submission could occur simultaneously.	In progress
6)	Seeking Resident to add on to ED STS	Alissa and I are still coordinating with Dr. Powers and Michelle to find an enthusiastic resident who will productively contribute to the study. We will likely add them on after iRIS approval and will wait until new residents arrive.	In progress
7)	Consent Form finalization	Consent form has been completed	Completed
8)	Nursing Research Council Meeting	Meeting to review NRC submission will occur on 7/15. All relevant parties have received the agenda and the scheduled meeting will occur over WebX from 12:00pm – 3:00pm. Will coordinate who will be attending during Monday morning huddle (and possibly over weekend)	In progress

Personal Items Dated:

S.No.	Action Item	Progress	Status
1)	Consenting Shadowing	After discussing with Alissa, and realizing that no qualitative, subjective assessments must be done, I will be required to shadow for 20 hours before I am approved to consent research subjects. I have begun shadowing both OASIS (Jamie) and COTI (Maris) consenting process.	In Progress

2)	Internship Practicum Research Proposal	Research Proposal has been finalized and approved by committee, with all necessary signatures and evaluations completed and submitted by the appropriate deadline.	Completed
3)	Creating Templates for Appendices and navigating REDCap questionnaire generation	Alissa and I are working together to further elaborate on protocol.	Completed
4)	Coordinating Meeting Date for Internship Practicum Research Defense	During the upcoming week I will be coordinating with Dr. Warren and Dr. Powers to confirm a dating for my practicum defense in late October or early November.	In Progress

Weekly Update

Week: 7/15 – 7/19
Name: Geordi Cortez-Neavel
Title: Clinical Research Intern
Educational Status: BA

Assigned Projects	Assigned Publications	Miscellaneous	Meetings
• ED STS	• ED STS – Outcome • ED STS – Methods • ED STS – Review/Meta Analysis	•	• Weekly Huddle • Weekly Team Meeting • Update Meeting for ED STS

IRB Study	Submission Type (CR, AE/SAE, etc.)	Submission Status	Outcome
ED STS	CR	Awaiting Submission (ready)	n/a

Weekly Progress Updates: (N/A)

- **Study One – N/A**
  - Recruitment/Follow-ups
    - Eligible/Approached:
    - Declined:
    - Consented/Interviewed:
    - Participants' emailed:
    - Follow-up Interviews:
- **Study One**
  - Recruitment/Follow-ups
    - Eligible/Approached:
    - Declined:
    - Consented/Interviewed:
    - Participants' emailed:
    - Follow-up Interviews:
- **See Action Items Below**

Publications: (N/A)

- **Paper One**
  - Not currently with me. See action items.

Any Hiccups/Road Blocks That Need Dept. Assistance:

- Not at this time

Action Items Dated:

S.No.	Action Item	Progress	Status
1)	Nursing Research Council Meeting	Presented to the Nursing Research Council with Alissa Old Crow and approved (with sign-off) for iRIS submission	Completed
2)	Co-Facilitator Training	Co-Facilitator Training package has been processed and shipped and will arrive in a few days. Will begin training with Alissa Old Crow (who will shadow to refresh her experience)	In Progress
4)	Physician/Nurse Shadowing	Shadowing has begun. Will likely attend rounds on Tuesdays as well.	In Progress
5)	iRIS Submission	iRIS application submitted and awaiting approval. Minor amendments will be required upon approval to add Trenton Raff and Penny Huddleston, as well as modify some protocol language pertaining to off-site follow-up evaluations.	Complete

6)	Seeking Resident to add on to ED STS	Alissa and I are still coordinating with Dr. Powers and Michelle to find an enthusiastic resident who will productively contribute to the study. We will likely add them on after iRIS approval and will wait until new residents arrive.	In progress
7)	HRVB Resilience Operations Manual	Currently working to complete the operations manual prior iRIS approval. Using manuals from Police VR and OASIS to compare.	In Progress
8)	HRVB Regulatory Binder	Working to complete Regulatory Binder alongside Alissa Old Crow.	In progress

Personal Items Dated:

S.No.	Action Item	Progress	Status
1)	Consenting Shadowing	After discussing with Alissa, and realizing that no qualitative, subjective assessments must be done, I will be required to shadow for 20 hours before I am approved to consent research subjects. I have begun shadowing both OASIS (Jamie) and COTI (Maris) consenting process. Will continue to work towards completion.	In Progress
2)	Coordinating Meeting Date for Internship Practicum Research Defense	As Drs. Powers and Warren were absent this previous week, I will be looking to coordinate with Dr. Warren and Dr. Powers to confirm a dating for my practicum defense in late October or early November.	In Progress

Weekly Update

Week: 7/22 – 7/26
Name: Geordi Cortez-Neavel
Title: Clinical Research Intern
Educational Status: BA

Assigned Projects	Assigned Publications	Miscellaneous	Meetings
• ED STS	• ED STS – Outcome • ED STS – Methods • ED STS – Review/Meta Analysis	•	• Weekly Huddle • Weekly Team Meeting • Update Meeting for ED STS

IRB Study	Submission Type (CR, AE/SAE, etc.)	Submission Status	Outcome
ED STS	CR	Awaiting Submission (ready)	n/a

Weekly Progress Updates: (N/A)

- **Study One – N/A**
  - Recruitment/Follow-ups
    - Eligible/Approached:
    - Declined:
    - Consented/Interviewed:
    - Participants' emailed:
    - Follow-up Interviews:
- **Study One**
  - Recruitment/Follow-ups
    - Eligible/Approached:
    - Declined:
    - Consented/Interviewed:
    - Participants' emailed:
    - Follow-up Interviews:
- **See Action Items Below**

Publications: (N/A)

- **Paper One**
  - Not currently with me. See action items.

Any Hiccups/Road Blocks That Need Dept. Assistance:

- Not at this time

Action Items Dated:

S.No.	Action Item	Progress	Status
1)	iRIS Submission (awaiting approval)	Awaiting iRIS approval. Having checked our application with Alissa, it appears that we were denied expedited/exempt review and have been assigned the Red Group for full-board review.	In Progress
2)	Co-Facilitator Training	Co-Facilitator Training package has been processed and shipped and will arrive in a few days. Will begin training with Alissa Old Crow (who will shadow to refresh her experience)	In Progress
4)	Physician/Nurse Shadowing	Upcoming scheduled shadowing with Alissa is set for 7/29 with ICU and 8/6 with ED.	In Progress
5)	Seeking Resident to add on to ED STS	Alissa and I are still coordinating with Dr. Powers and Michelle to find an enthusiastic resident who will productively contribute to the study. We will likely add them on after iRIS approval and will wait until new residents arrive...	In Progress
6)	HRVB Resilience Operations Manual	Currently working to complete the operations manual prior iRIS approval. Using manuals from Police VR and OASIS to compare.	In progress
7)	HRVB Regulatory Binder	Working to complete Regulatory Binder alongside Alissa Old Crow.	In Progress
8)	REDCap Review	Reviewed and improved my ability to navigate REDCap with Alissa. Currently checking to see what needs updates before we are ready to begin study.	In progress

Personal Items Dated:

S.No.	Action Item	Progress	Status
1)	Consenting Shadowing	After discussing with Alissa, and realizing that no qualitative, subjective assessments must be done, I will be required to shadow for 20 hours before I am approved to consent research subjects. I have begun shadowing both OASIS (Jamie) and COTI (Maris) consenting	In Progress

		process. Will continue to work towards completion.	
2)	Coordinating Meeting Date for Internship Practicum Research Defense	As Drs. Powers and Warren were absent this previous week, I will be looking to coordinate with Dr. Warren and Dr. Powers to confirm a dating for my practicum defense in late October or early November.	In Progress
3)	PE Training with Dr. Powers	Participated in prolonged exposure therapy workshop led by Dr. Powers on 7/25.	Completed

Weekly Update

Week: 7/29 – 8/02
Name: Geordi Cortez-Neavel
Title: Clinical Research Intern
Educational Status: BA

Assigned Projects	Assigned Publications	Miscellaneous	Meetings
• ED STS	• ED STS – Outcome • ED STS – Methods • ED STS – Review/Meta Analysis	•	• Weekly Huddle • Weekly Team Meeting • Update Meeting for ED STS

IRB Study	Submission Type (CR, AE/SAE, etc.)	Submission Status	Outcome
ED STS	CR	Returned with Stipulations	n/a

Weekly Progress Updates: (N/A)

- **Study One – N/A**
  - Recruitment/Follow-ups
    - Eligible/Approached:
    - Declined:
    - Consented/Interviewed:
    - Participants' emailed:
    - Follow-up Interviews:

- **Study One**
    - Recruitment/Follow-ups
        - Eligible/Approached:
        - Declined:
        - Consented/Interviewed:
        - Participants' emailed:
        - Follow-up Interviews:
- **See Action Items Below**

Publications: (N/A)

- **Paper One**
    - Not currently with me. See action items.

Any Hiccups/Road Blocks That Need Dept. Assistance:

- Not at this time

Action Items Dated:

S.No.	Action Item	Progress	Status
1)	iRIS Returned Submission (working through stipulations)	As of this week we have resolved an issue that indicated Dr. Warren was missing training that would be required to move forward. (In fact, the training was designated for CTX and thus not relevant.) We are currently working on the stipulations returned by Dolores, as we discovered we are indeed on expedited review. However, Dolores failed to return our protocol or consent form edits, and we are awaiting contact from her regarding those documents.	In Progress
2)	Co-Facilitator Training	Co-Facilitator Training package was shipped without the suite address specifically designated for delivery. We did not receive a tracking number with the invoice and made multiple attempts at contacting HeartMath to resolve the issue. After receiving reply (and discovering that the package was never delivered and then shipped back) we are receiving an expedited delivery which should arrive 8//3 or 8/5	In Progress
4)	Physician/Nurse Shadowing	Upcoming scheduled shadowing with Alissa is set for 8/6 with ED. It is imperative that we also shadow 4 Roberts and 4 Truett so that each floor included in the study is aware of our presence and the existence of the study.	In Progress
5)	Seeking Resident to add on to ED STS	Alissa and I are still coordinating with Dr. Powers and Michelle to find an enthusiastic	In Progress

		resident who will productively contribute to the study. We will likely add them on after iRIS approval and will wait until new residents arrive. There has currently been no further progress	
6)	HRVB Resilience Operations Manual	Currently working to complete the operations manual prior iRIS approval. Using manuals from Police VR and OASIS to compare. This has been somewhat put on hold as we are rushing to complete other requirements that are more time sensitive.	In progress
7)	HRVB Regulatory Binder	Working to complete Regulatory Binder alongside Alissa Old Crow. The regulatory binder is almost completely up to date, but some documents require a returned IRB approval.	In Progress
8)	REDCap Workshop (w/ Estrella)	Learned many important things form Estrella during our REDCap workshop yesterday that will help in the dissemination of surveys and branching logic in our questionnaires.	Completed

Personal Items Dated:

S.No.	Action Item	Progress	Status
1)	Consenting Shadowing	I have currently completed about 1/3 of my required hours and will be prioritizing its completion over the next week. I have begun shadowing both OASIS (Jamie) and COTI (Maris) consenting process.	In Progress
2)	Coordinating Meeting Date for Internship Practicum Research Defense	As Drs. Powers and Warren were absent this previous week, I will be looking to coordinate with Dr. Warren and Dr. Powers to confirm a dating for my practicum defense in late October or early November.	In Progress
3)	Coordinating update meeitng	Alissa and I need to meet with Dr. Powers and Dr. Warren to cover recent events of HRVB Resilience.	In Progress
4)	GANTT Timeline	Working to complete an updated version of study timeline that works alongside timeline of my internship practicum	In Progress

Weekly Update

Week: 8/05 – 8/09
Name: Geordi Cortez-Neavel
Title: Clinical Research Intern
Educational Status: BA

Assigned Projects	Assigned Publications	Miscellaneous	Meetings
• ED STS	• ED STS – Outcome • ED STS – Methods • ED STS – Review/Meta Analysis	•	• Weekly Huddle • Weekly Team Meeting • Update Meeting for ED STS will occur 08/12

IRB Study	Submission Type (CR, AE/SAE, etc.)	Submission Status	Outcome
HRVB Resilience	CR	Submitted with Revisions	n/a

Weekly Progress Updates: (N/A)

- **Study One – N/A**
  - Recruitment/Follow-ups
    - Eligible/Approached:
    - Declined:
    - Consented/Interviewed:
    - Participants' emailed:
    - Follow-up Interviews:
- **Study One**
  - Recruitment/Follow-ups
    - Eligible/Approached:
    - Declined:
    - Consented/Interviewed:
    - Participants' emailed:
    - Follow-up Interviews:
- **See Action Items Below**

Publications: (N/A)

- **Paper One**
  - Not currently with me. See action items.

Any Hiccups/Road Blocks That Need Dept. Assistance:

- Not at this time

Action Items Dated:

S.No.	Action Item	Progress	Status
1)	iRIS Returned Submission (submitted)	Submitted our revised iRIS application and received an email from Dolores indicating receipt of all necessary items. Currently awaiting response.	In Progress
2)	Co-Facilitator Training	Package arrived with cofacilitator training. Completed as of 8/08	Completed
4)	Physician/Nurse Shadowing	Scheduled shadowing went well and Alissa and I used our experiences to further an action plan for how we will advertise and recruit for the study. Shadowing still needs to take place on 4 Roberts and 4 Truett.	In Progress
5)	Seeking Resident to add on to ED STS	Alissa and I are still coordinating with Dr. Powers and Michelle to find an enthusiastic resident who will productively contribute to the study. We will likely add them on after iRIS approval and will wait until new residents arrive. There has currently been no further progress.	In Progress
6)	HRVB Resilience Operations Manual	Currently working to complete the operations manual prior iRIS approval. Using manuals from Police VR and OASIS to compare. This has been somewhat put on hold as we are rushing to complete other requirements that are more time sensitive. No Change as of this week.	In progress
7)	HRVB Regulatory Binder	Working to complete Regulatory Binder alongside Alissa Old Crow. The regulatory binder is almost completely up to date, but some documents require a returned IRB approval. No Change as of this week.	In Progress
8)	REDCap Measures Review and Testing	REDCap measures have been reviewed and tested, with coding for score tallies and branching logic now included. Currently still awaiting the meeting with Powers and Warren to finalize demographics questionnaire before proceeding into final phases of REDCap review.	Completed

Personal Items Dated:

S.No.	Action Item	Progress	Status
1)	Consenting Shadowing	I have currently completed about 1/2 of my required hours and will be prioritizing its completion over the next week. I have begun shadowing both OASIS (Jamie) and COTI (Maris) consenting process.	In Progress
2)	Coordinating Meeting Date for Internship Practicum Research Defense	Internship Practicum Defense date has been finalized for 11/05 (a Tuesday) from 1-3pm	Completed
3)	Coordinating update meeitng	Meeting scheduled for 12pm on Monday, 8/12.	In Progress
4)	GANTT Timeline	Updated GANTT Timeline has been completed and sent out.	Completed

Weekly Update

Week: 8/12 – 8/16
Name: Geordi Cortez-Neavel
Title: Clinical Research Intern
Educational Status: BA

Assigned Projects	Assigned Publications	Miscellaneous	Meetings
• ED STS	• ED STS – Outcome • ED STS – Methods • ED STS – Review/Meta Analysis	•	• Weekly Huddle • Weekly Team Meeting

IRB Study	Submission Type (CR, AE/SAE, etc.)	Submission Status	Outcome
HRVB Resilience	CR	Submitted with Revisions (again)	n/a

Weekly Progress Updates: (N/A)

- **Study One – N/A**
  - Recruitment/Follow-ups
    - Eligible/Approached:
    - Declined:
    - Consented/Interviewed:
    - Participants' emailed:
    - Follow-up Interviews:
- **Study One**
  - Recruitment/Follow-ups
    - Eligible/Approached:
    - Declined:
    - Consented/Interviewed:
    - Participants' emailed:
    - Follow-up Interviews:
- **See Action Items Below**

Publications: (N/A)

- **Paper One**
  - Not currently with me. See action items.

Any Hiccups/Road Blocks That Need Dept. Assistance:

- Not at this time

Action Items Dated:

S.No.	Action Item	Progress	Status
1)	iRIS Returned Submission (submitted again 8/12)	Submitted a second revised iRIS application after receiving another set of stipulations. Awaiting iRIS approval	In Progress
2)	RECap Test Survey	Disseminated survey to team for feedback and then made edits corresponding to critiques.	Completed
4)	Physician/Nurse Shadowing	Alissa and I will shadow 4 Roberts on Monday or Tuesday (8/19 or 8/20). Still coordinating 4 Truett shadowing	In Progress
5)	Seeking Resident to add on to ED STS	Alissa and I are still coordinating with Dr. Powers and Michelle to find an enthusiastic resident who will productively contribute to the study. We will likely add them on after iRIS approval and will wait until new residents arrive. There has currently been no further progress.	In Progress

6)	HRVB Resilience Operations Manual	Currently working to complete the operations manual prior iRIS approval. Using manuals from Police VR and OASIS to compare. This has been somewhat put on hold as we are rushing to complete other requirements that are more time sensitive. No Change as of this week.	In progress
7)	HRVB Regulatory Binder	Working to complete Regulatory Binder alongside Alissa Old Crow. The regulatory binder is almost completely up to date, but some documents require a returned IRB approval. No Change as of this week.	In Progress
8) 9)	Follow-up meeting with Warren and Powers HRVB Triaging Tasks	Smoothed out the final aspects of study before proceeding. Polished study and prepared for initiation. Alissa and I met to coordinate final tasks to complete for the initiation of the study, including piloting the project which we will begin next week (most likely)	Completed In Progress

Personal Items Dated:

S.No.	Action Item	Progress	Status
1)	Consenting Shadowing	I have currently completed about 3/5 of my required hours and will be prioritizing its completion over the next week. I have begun shadowing both OASIS (Jamie) and COTI (Maris) consenting process.	In Progress
2)	Coordinating Meeting Date for Internship Practicum Research Defense	Internship Practicum Defense date has been finalized for 11/05 (a Tuesday) from 1-3pm	Completed

Weekly Update

Week: 8/19 – 8/23
Name: Geordi Cortez-Neavel
Title: Clinical Research Intern
Educational Status: BA

Assigned Projects	Assigned Publications	Miscellaneous	Meetings
• ED STS	• ED STS – Outcome • ED STS – Methods • ED STS – Review/Meta Analysis	•	• Weekly Huddle • Weekly Team Meeting • Final Checklist with Dr. Powers (8/22) • Monthly CTO Staff Meeting (on Compliance)

IRB Study	Submission Type (CR, AE/SAE, etc.)	Submission Status	Outcome
HRVB Resilience	CR	Submitted with revisions and answers to stipulations.	n/a

Weekly Progress Updates: (N/A)

- **Study One – N/A**
  - Recruitment/Follow-ups
    - Eligible/Approached:
    - Declined:
    - Consented/Interviewed:
    - Participants' emailed:
    - Follow-up Interviews:
- **Study One**
  - Recruitment/Follow-ups
    - Eligible/Approached:
    - Declined:
    - Consented/Interviewed:
    - Participants' emailed:
    - Follow-up Interviews:
- **See Action Items Below**

Publications: (N/A)

- **Paper One**
  - Not currently with me. See action items.

Any Hiccups/Road Blocks That Need Dept. Assistance:

- Not at this time

Action Items Dated:

S.No.	Action Item	Progress	Status
1)	iRIS Returned Submission (submitted again 8/23)	Received another set of stipulations that asked questions concerning removal of certain template items. Questions have been answered and resubmitted	Completed
2)	RECap Contact Log and Regulatory binder	Disseminated regulatory binder and contact logs to team for feedback and then made edits corresponding to critiques.	Completed
4)	Physician/Nurse Shadowing	Alissa and I shadowed on 4 Roberts on Wednesday made contact with 4 Truett	In Progress
5)	Seeking Resident to add on to ED STS	Alissa and I are still coordinating with Dr. Powers and Michelle to find an enthusiastic resident who will productively contribute to the study. We will likely add them on after iRIS approval and will wait until new residents arrive. There has currently been no further progress.	In Progress
6)	HRVB Resilience Operations Manual	Currently working to complete the operations manual prior iRIS approval. Using manuals from Police VR and OASIS to compare. This has been somewhat put on hold as we are rushing to complete other requirements that are more time sensitive. No Change as of this week.	In progress
7)	HRVB Regulatory Binder	Regulatory Binder has been returned after receiving edits from team and has been reviewed to be up to date. Will make any final changes after receiving iRIS approval	Completed
8)	Final Check-Off with Dr. Powers	Met with Dr. Powers to review concerns with consenting logistics and my programmatic concerns. Will likely have to change study proposal to a 5-week study.	Completed
9)	HRVB Triaging Tasks	Alissa and I met to coordinate final tasks to complete for the initiation of the study, including piloting the project which we will begin next week (most likely)	In Progress
10)	Progress Check-List	Creating a CRA checklist and corresponding REDCap checklist for researchers involved in study	In Progress
11)	Preparing Step-by-Step manual	Preparing an instructional manual with corresponding images for participants	In Progress

Personal Items Dated:

S.No.	Action Item	Progress	Status
1)	Consenting Shadowing	I have currently completed about 3/4 of my required hours and will be prioritizing its completion over the next week. I have begun shadowing both OASIS (Jamie) and COTI (Maris) consenting process.	In Progress
2)	Research Proposal Revision Meeting	Will meet with Dr. Mathew and Dr. Jones to cover roadblocks with iRIS and study delays and how to compensate in my research proposal	In Progress

Weekly Update

Week: 8/26 – 8/30
Name: Geordi Cortez-Neavel
Title: Clinical Research Intern
Educational Status: BA

Assigned Projects	Assigned Publications	Miscellaneous	Meetings
• ED STS	• ED STS – Outcome • ED STS – Methods • ED STS – Review/Meta Analysis	•	• Weekly Huddle • Weekly Team Meeting • Timeline Meeting with Dr. Powers (8/28)

IRB Study	Submission Type (CR, AE/SAE, etc.)	Submission Status	Outcome
HRVB Resilience	CR	**Submitted Revisions**	Active

Weekly Progress Updates: (N/A)

- **Study One – N/A**
    - Recruitment/Follow-ups
        - Eligible/Approached:
        - Declined:
        - Consented/Interviewed:
        - Participants' emailed:
        - Follow-up Interviews:
- **Study One**
    - Recruitment/Follow-ups
        - Eligible/Approached:
        - Declined:
        - Consented/Interviewed:
        - Participants' emailed:
        - Follow-up Interviews:
- **See Action Items Below**

Publications: (N/A)

- **Paper One**

- Not currently with me. See action items.

Any Hiccups/Road Blocks That Need Dept. Assistance:

- Not at this time

Action Items Dated:

S.No.	Action Item	Progress	Status
1)	iRIS Active and awaiting final approval	Received approval of study which is in active stage. Now just awaiting submitted revisions approval and final letter of approval.	In Progress
2)	RECap Contact Log and Regulatory binder	Final edits to both contact log and regulatory binder	In Progress
3)	Seeking Resident to add on to ED STS	Alissa and I are still coordinating with Dr. Powers and Michelle to find an enthusiastic resident who will productively contribute to the study. We will likely add them on after iRIS approval and will wait until new residents arrive. There has currently been no further progress.	In Progress
4)	HRVB Resilience Operations Manual	Currently working to complete the operations manual prior iRIS approval. Using manuals from Police VR and OASIS to compare. This has been somewhat put on hold as we are rushing to complete other requirements that are more time sensitive. No Change as of this week.	In progress
5)	HRVB Regulatory Binder	Regulatory Binder has been returned after receiving edits from team and has been reviewed to be up to date. Will make any final changes after receiving iRIS approval	Completed
6)	HRVB Triaging Tasks	Alissa and I met to coordinate final tasks to complete for the initiation of the study, including piloting the project which we will begin next week (most likely)	Completed
7)	Progress Check-List	Creating a CRA checklist and corresponding REDCap checklist for researchers involved in study.	Completed
8)	iRIS Revisions	Alissa and I prepared iRIS revisions to protocol, measures, and ICF.	Completed
9)	Preparing Step-by-Step manual	Preparing an instructional manual with corresponding images for participants. Handed off final review of step-by-step to Alissa.	In Progress

Personal Items Dated:

S.No.	Action Item	Progress	Status
1)	Consenting Shadowing	I have currently completed about 3/4 of my required hours and will be prioritizing its completion over the next week. I have begun shadowing both OASIS (Jamie) and COTI (Maris) consenting process.	In Progress
2)	Research Proposal Revision Meeting	Meeting went well and I received approval to shorten study to 5 weeks on my program's side.	Completed

Weekly Update

Week: 9/03 – 9/06
Name: Geordi Cortez-Neavel
Title: Clinical Research Intern
Educational Status: BA

Assigned Projects	Assigned Publications	Miscellaneous	Meetings
• ED STS	• ED STS – Outcome • ED STS – Methods • ED STS – Review/Meta Analysis	•	• Weekly Huddle • Weekly Team Meeting • Finance Meeting with Nurse Researchers (9/5)

IRB Study	Submission Type (CR, AE/SAE, etc.)	Submission Status	Outcome
HRVB Resilience	CR	**Submitting Revisions**	Active

Weekly Progress Updates: (N/A)

- **Study One – N/A**
    - Recruitment/Follow-ups
        - Eligible/Approached:

        - Declined:
        - Consented/Interviewed:
        - Participants' emailed:
        - Follow-up Interviews:
- **Study One**
    - Recruitment/Follow-ups
        - Eligible/Approached:
        - Declined:
        - Consented/Interviewed:
        - Participants' emailed:
        - Follow-up Interviews:
- **See Action Items Below**

Publications: (N/A)

- **Paper One**
    - Not currently with me. See action items.

Any Hiccups/Road Blocks That Need Dept. Assistance:

- Not at this time

Action Items Dated:

S.No.	Action Item	Progress	Status
1)	iRIS Active and awaiting final approval	Received approval of study which is in active stage. Now just awaiting submitted revisions approval and final letter of approval. After talking briefly with Dr. Warren, we discovered a roadblock in financing. Working to resolve now.	In Progress
2)	RECap Contact Log and Regulatory binder	Final edits to both contact log and regulatory binder. Sent out REDCap to team for final audits and have run through comments and made appropriate changes.	Complete
3)	Seeking Resident to add on to ED STS	Alissa and I are still coordinating with Dr. Powers and Michelle to find an enthusiastic resident who will productively contribute to the study. We will likely add them on after iRIS approval and will wait until new residents arrive. There has currently been no further progress.	In Progress
4)	HRVB Resilience Operations Manual	Currently working to complete the operations manual prior iRIS approval. Using manuals from Police VR and OASIS to compare. This has been somewhat put	In progress

		on hold as we are rushing to complete other requirements that are more time sensitive. No Change as of this week.	
5)	HRVB Regulatory Binder	Regulatory Binder has been returned after receiving edits from team and has been reviewed to be up to date. Will make any final changes after receiving iRIS approval.	Completed
6)	HRVB Mock Presentations	Pilot presentations to team and other staff began on Wednesday and occurred again on Friday. We are working to make changes/edits according to feedback	In Progress
7)	Progress Check-List	Creating a CRA checklist and corresponding REDCap checklist for researchers involved in study. Working now to create updated checklists based on new changes to protocol.	In Progress
8)	iRIS Revisions	Alissa and I prepared iRIS revisions to protocol, measures, and ICF. New ones are currently In progress.	In Progress
9)	Preparing Step-by-Step manual	Preparing an instructional manual with corresponding images for participants. Handed off final review of step-by-step to Alissa, which we've approved for use by providers during presentation.	Completed

Personal Items Dated:

S.No.	Action Item	Progress	Status
1)	Consenting Shadowing	I have currently completed about 4/5 of my required hours and will be prioritizing its completion over the next week. I have begun shadowing both OASIS (Jamie) and COTI (Maris) consenting process. I will check off with Michelle Acker next week.	In Progress

Weekly Update

Week: 9/16 – 9/20
Name: Geordi Cortez-Neavel
Title: Clinical Research Intern
Educational Status: BA

Assigned Projects	Assigned Publications	Miscellaneous	Meetings
• HRVB Resilience	• HRVB Resilience – Outcome • HRVB Resilience – Methods • HRVB Resilience – Review/Meta Analysis	•	• Weekly Huddle • Weekly Team Meeting • Recruitment Meeting with Dr. Powers (9/19)

IRB Study	Submission Type (CR, AE/SAE, etc.)	Submission Status	Outcome
HRVB Resilience	CR	**Active (open to enrollment)**	Active

Weekly Progress Updates: (N/A)

- **Study One – N/A**
  - Recruitment/Follow-ups
    - Eligible/Approached:
    - Declined:
    - Consented/Interviewed:
    - Participants' emailed:
    - Follow-up Interviews:
- **Study One**
  - Recruitment/Follow-ups
    - Eligible/Approached:
    - Declined:
    - Consented/Interviewed:
    - Participants' emailed:
    - Follow-up Interviews:
- **See Action Items Below**

Publications: (N/A)

- **Paper One**
  - Not currently with me. See action items.

Any Hiccups/Road Blocks That Need Dept. Assistance:

- Not at this time

Action Items Dated:

S.No.	Action Item	Progress	Status
1)	HRVB Study Revision	Revision of study submitted and approved; study is not open for enrollment.	Completed
2)	HRVB Recruitment Flyers	Alissa and I have gone to each floor to put up flyers. As of our last check, we counted 27 tabs in total have been taken. No calls for consenting as of yet.	In Progress
3)	Seeking Resident to add on to ED STS	Alissa and I are still coordinating with Dr. Powers and Michelle to find an enthusiastic resident who will productively contribute to the study. We will likely add them on after iRIS approval and will wait until new residents arrive. There has currently been no further progress.	In Progress
4)	HRVB Resilience Operations Manual	Currently working to complete the operations manual prior iRIS approval. Using manuals from Police VR and OASIS to compare. This has been somewhat put on hold as we are rushing to complete other requirements that are more time sensitive. No Change as of this week.	In progress
5)	HRVB Huddle Pitches	Alissa and I have been attending morning and evening huddles to present to providers on the 4 designated floors	In Progress
6)	HRVB Mock Presentations	Pilot presentations to team and other staff began on Wednesday and occurred again on Friday. We are working to make changes/edits according to feedback. Final Changes have been made and completed.	Completed
7)	Progress Check-List	Creating a CRA checklist and corresponding REDCap checklist for researchers involved in study. Working now to create updated checklists based on new changes to protocol. Final Checklist revised and completed.	Completed

Personal Items Dated:

S.No.	Action Item	Progress	Status
1)	Consenting Shadowing	Completed Consent Shadowing and signed off with Michelle Acker earlier on Monday	Complete

Weekly Update

Week: 10/7/19 - 10/13/19
Name: Geordi Cortez-Neavel
Title: Clinical Research Student Intern

Meetings: N/A

Publications:

- **Internship Practicum Thesis (1st Draft)**
  - Not currently with me. See action items.

New Action Items Dated:

S.No.	Action Item	Progress	Date Started
1)	Submitting Internship Practicum Thesis Draft	Will be submitted by end of this week. I will then begin revising to produce final draft.	9/30/19
2)	HRVB Recruitment	Currently recruited 5 participants with plans to recruit 3 more by early next week. Alissa and I plan to invest more time next week towards recruitment.	9/30/19

Ongoing Action Items Dated:

S.No.	Action Item	Progress	Date Started
1)	HRVB Recruitment Flyers	As of October 3rd, Alissa and I have counted 67 tabs pulled from flyers.	N/A
2)	HRVB Resilience Operations Manual	Currently working to complete the operations manual prior iRIS approval. Using manuals from Police VR and OASIS to compare. This has been somewhat put on hold as we are rushing to complete other requirements that are more time sensitive. No Change as of this week.	N/A
3)	HRVB Huddle Pitches	Alissa and I have decided to halt huddle pitches and begin rounding on floors instead. The decision was made after attending multiple huddles on each floor.	N/A

Weekly Update

Week: 10/14/19 - 10/20/19
Name: Geordi Cortez-Neavel
Title: Clinical Research Student Intern

Meetings: Met with Nurse Directors of ED on 10/17 and 10/18 to discuss recruitment

Publications:

- **Internship Practicum Thesis (2nd Draft)**
  - Not currently with me. See action items.

New Action Items Dated:

S.No.	Action Item	Progress	Date Started
1)	Meeting with Nurses on 4T and 4R next week	Scheduled meeting for Tuesday, 10/22, from 3:00-3:30 on 4T and working to schedule meeting with Bobby Leeper on 4R.	10/16
2)	Know Your Why reading	Began reading through the "Know Your Why" book in preparation for developing office mission statement.	10/14

Ongoing Action Items Dated:

S.No.	Action Item	Progress	Date Started
1)	HRVB Recruitment Flyers	As of October 3rd, Alissa and I have counted 67 tabs pulled from flyers. We will do a final round of flyer checks next week (10/21-10/27)	N/A
2)	HRVB Resilience Operations Manual	Currently working to complete the operations manual prior iRIS approval. Using manuals from Police VR and OASIS to compare. This has been somewhat put on hold as we are rushing to complete other requirements that are more time sensitive. No Change as of this week.	N/A
3)	HRVB Recruitment	Currently recruited 14 participants with plans to recruit 4-5 more by end of weekend. Alissa and I have begun seeking out Trenton-equivalents on 4T, 4T, and ED (re: quality nurses, nurse directors, and charge nurses). We will	9/30/19

		have these nurses function as points of contact for participant recruitment in future efforts; they will either provide us with names of potential participants who have verbalized that they wish to be approached, or walk with us around floors to assist in recruitment.	
4)	Continued work on Internship Practicum Thesis Draft	Currently working on thesis drafts for my Internship Practicum defense. Submitted another draft to major advisor on Tuesday, 10/15, but still awaiting response. Draft must be sent out by 10/22 to all committee members to view. Will require an increasingly greater amount of my time as I get closer to my defense on November 5th.	9/30/19

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