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# HEALTH BEHAVIORS IN MILITARY VETERANS WITH AND WITHOUT POSTTRAUMATIC STRESS DISORDER

by

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A thesis submitted in partial fulfillment of the requirements for the degree of Master of Science in the Department of Psychology in the College of Sciences at the University of Central Florida Orlando, Florida

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### ABSTRACT

A link between posttraumatic stress disorder and health behaviors, such as exercise, alcohol, smoking, and caffeine has been suggested. However, it is unknown whether veterans with combat-related PTSD differ from combat veterans without PTSD and whether health behaviors change over the course of exposure therapy for PTSD or differ based on PTSD severity. This study examined the relationship between health behaviors and PTSD. More specifically, combat veterans with and without PTSD were compared across self-reported levels of alcohol use, smoking, exercise, and caffeine. Health behaviors of combat veterans with PTSD were compared before and after a 17-week treatment for PTSD. Results showed a significant number of participants decreased alcohol use at post-treatment by an average of eight drinks over 30 days, regardless of their PTSD severity level or amount of improvement in PTSD symptoms. No significant differences were found for other health behaviors.

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#### **CHAPTER 1: INTRODUCTION**

#### 1.1 <u>Posttraumatic Stress Disorder</u>

Posttraumatic Stress Disorder (PTSD) is a psychological disorder involving a maladaptive reaction to a traumatic event, characterized by intrusive memories or dreams of the trauma, avoidance of trauma reminders, negative changes in cognitions or mood, and increased arousal and reactivity associated with reminders of the trauma (American Psychiatric Association, 2013). Point prevalence estimates of PTSD among Operation Enduring Freedom (OEF; Afghanistan) and Operation Iraqi Freedom (OIF; Iraq) veterans are estimated to be 12-13% (Kok, Herrell, Thomas, & Hoge, 2012),10-12% in Gulf war veterans (Kang, Natelson, Mahan, Lee, & Murphy, 2003) and may be as high as 31% in Vietnam veterans (Kulka et al., 1990). As of 2003, over 200,000 veterans have received disability payments for PTSD, with claims, on average, more than three times the national average of other non-PTSD related claims, totaling about \$20,000 per year per claim (Hunter et al., 2006).

In addition to the large economic burden associated with PTSD, the disorder is also associated with comorbidities (Galatzer-Levy, Nickerson, Litz, & Marmar, 2013). In civilians with PTSD, 82% have at least one comorbid psychiatric diagnosis (Brady, Killeen, Brewerton, & Lucerini, 2000). Most common comorbid diagnoses include substance abuse or dependence, depression and other mood disorders, and anxiety disorders (Brady et al., 2000). Not surprisingly, functional outcomes are poorer among those with PTSD with at least one comorbid diagnosis as compared to PTSD alone (Galatzer-Levy et al., 2013). Additionally, PTSD is associated with negative health outcomes. Studies have shown that veterans with PTSD report greater negative health behaviors and more physical problems (Beckham et al., 1998; Kimerling, Clum, & Wolfe, 2000; Wagner, Wolfe, Rotnitsky, Proctor, & Erickson, 2000), poorer functional outcomes (Kimerling et al., 2000; Wagner et al., 2000), and increased healthcare utilization (Marshall, Jorm, Grayson, & O'Toole, 1998) compared to veterans without PTSD. For example, in female Vietnam veterans, PTSD symptoms accounted for 16% of the variance in self-reported health problems (Kimerling et al., 2000). In male and female Gulf War veterans, PTSD symptomatology significantly predicted self-reported health problems 24 months after initial assessment, regardless of amount of combat exposure (Wagner et al., 2000). These associations have been found in veterans of many conflicts, including Vietnam (Marshall, Jorm, Grayson, & O'Toole, 1998), the Persian Gulf War (Wagner et al., 2000), and OEF/OIF (Bray et al., 2010; Hoerster et al., 2012; Jacobson et al., 2008) as well as in civilians with PTSD (Weisberg et al., 2014; Zen, Whooley, Zhao, & Cohen, 2012). Additionally, Weisberg and colleagues (2014) found that civilians with PTSD seem to have more current and lifetime medical conditions than either those with anxiety disorders but no PTSD or those who experienced a traumatic event but did not have a mental health diagnosis. PTSD has been found to be a better predictor of the number of reported medical problems than actual number of physical injuries, trauma history, lifestyle factors, or comorbid depression (Weisberg et al., 2014). Substance use, amont of exercise, and tobacco use did not predict reported number of medical problems. The reason for these relationships is not known; however, study authors hypothesized that individuals with PTSD are more likely to over report medical problems or that PTSD is associated with physical changes likely to lead to medical complications, such as HPA-axis dysregulation. Interestingly, those with PTSD were no more likely to report symptoms consistent with somatization disorder (headache, dizziness) than other participants (Weisberg et al., 2014). In addition to general health complaints, PTSD has also been linked to physical health through behaviors such elevated

alcohol consumption, smoking, lack of exercise, and elevated caffeine intake (Assis et al., 2008; Hoerster et al., 2012; Jacobson et al., 2008). Understanding how these behaviors may change over the course of PTSD treatment may allow them to be more specifically targeted.

#### 1.2 <u>Alcohol</u>

Research shows an established link between alcohol consumption and PTSD in both civilians and veterans. One study examining the relationship between PTSD and substance use in civilians found that when comparing those formerly diagnosed with PTSD (but currently not meeting criteria with those meeting criteria for PTSD), a current diagnosis was associated with an 11% increase in probability of a diagnosis of alcohol dependence (Ouimette, Read, Wade, & Tirone, 2010).

This relationship has also been documented in military service members and veterans. One study of active duty, veteran, National Guard/Reserve, and civilian men found that active duty and veteran men were more likely to endorse heavy drinking (as defined by greater than two drinks per day) than National Guard/Reserve or civilian men (Hoerster et al., 2012). Further, Jacobson and colleagues (2008) looked at risk factors for problem drinking in a study of 48,481 Active Duty, National Guard, and Reserve members from all branches of the military and found that when comparing health behaviors pre- and post-deployment, a higher percentage of those in the Reserves or National Guard had a new onset of unhealthy drinking behaviors post deployment as compared to active duty personnel. Neither study reported amount of combat seen by participants or number of deployments. Although findings are mixed as to whether Active

Duty or Reserves/National Guard members exhibit more problematic drinking, both studies show higher levels of problematic drinking in military personnel versus civilians.

Not surprisingly, there has been a link between direct combat exposure and alcohol misuse. In one study, veterans who reported alcohol misuse were more likely to have experienced direct combat exposure than those who had not (Jakupcak et al., 2010). Jacobson and colleagues (2008) found that Reserve/Guard members who deployed and endorsed combat exposure were more likely to endorse new-onset heavy weekly drinking, binge drinking, and alcohol-related problems than those who did not deploy. However, active duty military members who deployed and endorsed combat exposure were at increased odds for new drinking but not for binge drinking or drinking problems (Jacobson et al., 2008). The reason for this change is unknown. Further, the study found that at the 2-year follow-up, there was an increased risk for onset of drinking problems, including drinking in spite of physician guidance to stop drinking due to health reasons, interference with daily responsibilities due to drinking, being drunk or hung-over during daily responsibilities, having difficulty getting along with others due to drinking, or driving with a blood alcohol content above the legal limit among those who had any mental health diagnosis/subclinical symptoms or psychotropic medications, regardless of duty status or deployment history. Though these studies demonstrate the link between combat experience and problematic alcohol use, they do not address how these behaviors may change as a result of psychotherapeutic intervention for PTSD.

Studies of OIF/OEF veterans have found that veterans diagnosed with PTSD were significantly more likely to misuse alcohol than veterans who did not meet diagnostic criteria for PTSD (Jacobson et al., 2008; Jakupcak et al., 2010). Jacobson and colleagues (2008) found those that scored the highest on problem drinking questions also reported PTSD, subclinical PTSD, or

depressive symptoms (and were smokers), indicating that in military veterans, symptoms of PTSD are associated with problematic drinking. Additionally, those diagnosed with PTSD were at increased odds of developing an alcohol-related problem at the 2-year follow-up (Jacobson et al., 2008).

Alcohol consumption seems to increase as reported PTSD symptoms increase. Jakupcak and colleagues (2010) found that more severe emotional numbing symptoms were associated with alcohol misuse and alcohol-related problems, including drinking in spite of physician guidance to stop, interference with daily responsibilities, being drunk or hung-over during daily responsibilities, having difficulty getting along with others due to drinking, or driving with a blood alcohol content above the legal limit (Jacobson et al., 2008). However, the study did not treat PTSD symptoms or examine how alcohol consumption or alcohol-related problems changed as PTSD symptoms changed. In addition, this study examined alcohol misuse defined by alcohol-related problems but did not examine subthreshold unhealthy drinking, such as binge drinking with little to no occupational or social interference. Such difficulties may also be associated with PTSD.

Further, among those comorbid for PTSD and substance use disorder diagnoses, receiving PTSD treatment is associated with higher odds of being in remission 5-years post discharge from a substance use treatment facility as compared to those who did not receive PTSD treatment (Ouimette, Moos, & Finney, 2003), indicating that addressing PTSD symptoms is helpful for those who wish to decrease substance use.

#### 1.3 Smoking

The relationship between smoking, trauma, PTSD, and military service is complex. Generally, it has been found that military members endorse higher rates of smoking than civilians. One fairly recent study found the rate of smoking in a civilian male population is 19.5% (Hoerster et al., 2012). Although veterans and National Guard members/Reservists seem to have slightly lower rates (17.4% and 14.4%, respectively), active duty military members were found to have a 23.4% rate of smoking (Hoerster et al., 2012). In addition, once demographic variables including age, race/ethnicity, marital status, education, income, and region were controlled for, veterans also showed higher rates of smoking than civilians (Hoerster et al., 2012).

Early research showed that combat veterans with PTSD have higher rates of smoking than those without a PTSD diagnosis (Beckham et al., 1995). However, a later study found similar rates of smoking in combat veterans regardless of PTSD diagnosis (Beckham et al., 1997). Importantly, differences may be related to total amount smoked rather than percentage of smokers. Beckham and colleagues (1997) found that veteran smokers diagnosed with PTSD smoked more than veteran smokers not diagnosed with PTSD, and this finding has been supported in subsequent studies (Lasser et al., 2000; Buckley, Susannah, Bedard, Dewulf, & Greif, 2004). Furthermore, equivalent rates of smoking in Vietnam veterans regardless of PTSD diagnosis could be a cohort effect (Kirby et al., 2008), as a greater percentage of the population in the United States smoked in the 1970's (during the Vietnam war) than in the 2000's and 2010's, during the OEF and OIF conflicts (US Department of Health and Human Services, 2004). Additionally, Vietnam veterans who report heavy smoking endorse higher severity of PTSD than those who report light smoking (Beckham et al., 1995). Further, Beckham and

colleagues (1995) found that Vietnam veterans who endorse any level of smoking endorse higher levels of PTSD than nonsmokers (Beckham et al., 1995).

When examining trauma and smoking, current smokers endorse higher rates of trauma than non-smokers (Feldner et al., 2007). Additionally, it has been shown that among traumaexposed civilians, those diagnosed with PTSD reported heavier smoking than those without a PTSD diagnosis, a relationship which holds after controlling for variables including state anxiety, depressive symptoms, and level of traumatic event exposure (Feldner et al., 2007, Vujanovic, Farris, Harte, Smits, & Zvolensky 2012). In a study of smoking patterns and mental health symptoms in civilians, greater nicotine dependence was related to higher depressive and PTSD symptoms (Weaver & Etzel, 2003). Similar findings have been documented in military veterans. In one study of Vietnam Veterans, heavier smokers generally endorsed higher severity of PTSD symptoms than non-heavy smokers or nonsmokers (Beckham et al., 1995).

Additionally, smoking has been shown to increase after trauma reminders. One study exposed smokers with PTSD and without PTSD to reminders of their traumatic event and neutral events, then allowed them to smoke. Smokers with PTSD rated negative affect as higher than those without after trauma reminders and had greater puff volume, indicating that increased negative affect after a trauma reminder is associated with higher rates of smoking (McClernon, Beckham, Mozley, Feldman, Vrana, & Rose, 2004).

Despite the multitude of studies examining smoking and PTSD, there has been relatively little focus on whether smoking changes as a result of specific PTSD intervention. Smokers with PTSD show lower rates of cessation than smokers with other psychological comorbidities (Lasser et al., 2000). Few studies have examined outcomes of smoking behavior after treatment for PTSD. Feldner and colleagues (2013) administered psychotherapy and smoking cessation

treatment to participants with PTSD. They found that some participants reduced their smoking after treatment. However, participants were not combat veterans, and psychotherapy was not exposure, specifically. Finally, the study was limited by small sample size. A similar study of veterans found that integrating smoking cessation treatment into PTSD treatment improved smoking cessation outcomes as compared to PTSD and smoking cessation therapy administered separately (McFall et al., 2005); however, the study did not specify what treatment was used for PTSD. Conversely, another study's results indicated that the rate of cigarette use did not decline once PTSD was no longer diagnosed (Vlahov et al., 2004). However, this has not been examined in a population receiving an evidence-based treatment for PTSD. Elucidating a mechanism underlying cigarette smoking and PTSD may help aid the development of targeted treatments in order to improve smoking cessation rates in this population. There are no prospective studies of smoking and trauma exposure, so it is not yet known what group differences exist in smokers versus nonsmokers before development of PTSD. Additionally, it is not yet known what causes the relationship between increased smoking and PTSD.

A study of civilians with PTSD found that higher levels of PTSD symptoms were associated with more smoking, and that the primary motivation for smoking among this group was to reduce negative affect (Feldner et al., 2007). Similarly, Vietnam veterans reported a higher rate of smoking after reminder of military experiences (Beckham et al., 1995), suggesting that stress or anxiety may lead to increased smoking among current smokers. However, it is not known if smoking would change once stress and anxiety related to trauma reminders decreased.

#### 1.4 Exercise

Exercise likely plays a role in mental health. Studies support its efficacy in reducing depressive symptoms, subjective stress, and suicidality in civilians (Berger & Owen, 1988; Davidson, Babson, Bonn-Miller, Souter, & Vannoy, 2013; Newman & Motta, 2007; Rutter, Weatherill, Krill, Orazem, & Taft, 2013; Salmon, 2001). In addition, studies support exercise as producing anxiolytic effects in mice (Duman, Schlesinger, Russell, & Duman, 2008; Salam et al., 2009) and humans (Byrne & Byrne, 1993).

In general, anxiety disorders have been shown to be less common among those reporting habitual physical activities as opposed to those who do not habitually exercise (Goodwin, 2003). Studies have found that exercise improves symptoms of agoraphobia (Martinsen, Hoffart, & Solberg, 1989), panic disorder (Broocks et al., 1998), obsessive compulsive disorder (Abrantes et al., 2009; Brown et al., 2007; Knapen et al., 2009), generalized anxiety disorder (Martinsen, Hoffart, & Solberg, 1989; Merom et al., 2008; Herring, Jacob, Suveg, Dishman, & O'Connor, 2012), and social anxiety disorder (Herring et al., 2012; Martinsen, Hoffart, & Solberg, 1989).

More specifically, there is an association between exercise and PTSD. Implementation of an exercise regimen was shown to reduce PTSD symptoms in children (Motta, McWilliams, Schwartz, & Cavera, 2012; Newman & Motta, 2007; Streeter, Gerbarg, Saper, Ciraulo, & Brown, 2012). In a study of PTSD severity and exercise habits in civilians, those with the most severe PTSD symptoms reported the lowest exercise levels (Vujanovic, Farris, Harte, Smits, & Zvolensky, 2013). Assis and colleagues (2008) found that there might be a decrease in physical activity after development of PTSD, rather than a characteristic present before PTSD onset. They assessed current physical activity levels and premorbid physical activity levels in Brazilian civilians with PTSD (Assis et al., 2008) and found that 50% of participants endorsed regular participation in physical activity before development of PTSD, and 26% were classified as physically active according to American College of Sports Medicine (ACSM) guidelines. However, after development of PTSD, only 22% endorsed regular physical activity, and 14% were classified as physically active according to ACSM guidelines (Assis et al., 2008). When asked about their change in activity level, participants reported lack of motivation and lack of time. Interestingly, the number of participants who reported enjoying exercise did not change from pre-PTSD ratings to PTSD ratings. In addition, no participant had a physical condition which would preclude participation in physical activity. However, it is not known how exercise levels would change, if at all, after participants received therapy to address PTSD symptoms, nor has this relationship been confirmed in a veteran population.

#### 1.5 <u>Caffeine</u>

No research could be found regarding caffeine consumption habits in those with PTSD or how they differ, if at all, from those without PTSD. However, veterans may use high rates of caffeine to compensate for poor sleep quality and fatigue. It is estimated that 74-90% of currently and previously deployed veterans report poor sleep quality (Babson, Blonigen, Boden, Drescher, & Bonn-Miller, 2012; Lewis, Creamer, & Failla, 2009), and those with PTSD report worse sleep quality than those without PTSD (Lewis et al., 2009). Caffeine is commonly used to combat

fatigue and improve mental alertness (Lorist & Tops, 2003; Olsen, 2013), so it may be hypothesized that veterans are using caffeine at high levels than non-veterans and that combat veterans use caffeine more than non-combat-exposed veterans. Additionally, caffeine can contribute to anxiety (Bruce, Scott, Shine, & Lader, 1992). If combat veterans are using a high amount of caffeine, this may increase their anxiety related to traumatic situations or overall distress level. trauma reminders decreased.

#### 1.6 <u>Summary</u>

In summary, the extant literature suggests an association between PTSD and negative health behaviors, including alcohol, smoking, exercise, and possibly, caffeine. However, it is not known how these health behaviors change as a result of treatment for PTSD symptoms. This may be integral to understanding and explaining the PTSD-negative health behavior relationship and providing patients with most effective treatments. However, this has not yet been empirically investigated. This study was designed to (1) determine if OIF/OEF combat veterans with PTSD have higher levels of negative health behaviors than OIF/OEF veterans without PTSD, (2) determine if health behaviors change after participants undergo PTSD treatment, and (3) determine if changes in health behaviors are related to changes in PTSD symptoms. It was hypothesized that combat veterans with PTSD, that negative health behaviors (alcohol, smoking, inactivity, and caffeine consumption) would decrease significantly after PTSD treatment, and that negative health behaviors are related to PTSD symptomatology.

#### **CHAPTER 2: METHODS**

#### 2.1 <u>Research Design</u>

This study utilized two groups of participants: (1) combat veterans with no diagnosis of PTSD (PTSD-) and (2) combat veterans diagnosed with PTSD (PTSD<sub>+</sub>), and sought to answer two primary questions: (1) do veterans with PTSD have greater negative health behaviors than the PTSD- group? And (2) do negative health behaviors change as a result of 17 weeks of treatment for PTSD? The between-groups analysis compared health behaviors of the PTSD<sub>+</sub> group to the PTSD- group in order to determine if levels of negative health behaviors are higher in the PTSD<sub>+</sub> group. The within-groups analysis evaluated whether health behaviors changed after a 17-week course of exposure therapy for PTSD.

#### 2.2 Participants

In this study, veterans were defined as military personnel who served in combat during OEF/OIF/OND operations. The PTSD<sub>+</sub> group (n = 120) was drawn from an ongoing DoD-funded treatment study entitled "Trauma Management Therapy for OIF/OEF Veterans" (TMT) that was supported by USAMRMC-MOMRP contract award number W81XWH-11-2-0038. Participants in this study received 14 individual exposure sessions and 14 session of group therapy over a 17 week period. The PTSD- group was recruited using flyers and by attending veteran outreach events. The PTSD- group (n = 24) was assessed by structured interview to affirm no current or past diagnosis for PTSD.

#### 2.3 Inclusion and Exclusion Criteria

Participants were required to meet specific inclusion and exclusion criteria as follows:

- The Clinician-Administered PTSD Scale (CAPS; Blake et al., 1990) was used to evaluate all participants for whether they currently met criteria for DSM-IV-TR (APA, 2000) diagnosis of PTSD. All participants in the PTSD<sub>+</sub> group met diagnostic criteria and had PTSD symptom duration of at least six months. Participants in the PTSD- group did not meet DSM-IV-TR diagnosis of PTSD.
- 2. All participants were combat veterans as validated by DD-214 documentation.
- 3. All participants were 18 years of age or older.
- 4. Participants in the PTSD- group were excluded for current diagnosis of psychosis, active substance abuse or dependence, antisocial personality disorder, or PTSD. Participants in the PTSD+ group were excluded for substance abuse or dependence, antisocial personality disorder, psychotic disorders, or a primary disorder other than PTSD.
- 5. All participants taking benzodiazepine medication (e.g., Xanax, Valium, and Klonopin) within 24 hours prior to study participation were excluded. Benzodiazepines work in the central nervous system to increase y-aminobutyric acid (GABA) inhibitory signals that may interfere with neural responses to anxiety-provoking stimuli, thus interfering with the exposure therapy in the parent study. Participants on SSRI antidepressants were included in both groups. Participants in the PTSD+ group were asked to complete a medication log on a weekly basis in order for medications to be tracked.

Participants in the PTSD+ group were included based on participation in an exposurebased treatment in an ongoing randomized clinical trial for treating combat-related PTSD

(TMT). All of the study procedures were approved by the UCF Institutional Review Board (IRB).

#### 2.4 <u>Measures</u>

#### 2.4.1 All Combat Veterans (PTSD+ and PTSD-)

The *Clinician-Administered PTSD Scale* (CAPS; Blake et al., 1990; Blake et al., 1995; Weathers et al., 2001) was used to assess for presence of PTSD and overall severity of PTSD, if present. The CAPS has sound psychometric properties with inter-rater reliability scores consistently above .90, convergent validity scores ranging from r = .70-.90 with self-report measures for PTSD, and observed sensitivity and specificity at .80 or higher (Weathers, Keane, & Davidson, 2001). The CAPS measures the frequency and intensity of the 17 symptoms for PTSD required by the DSM-IV on a 0 to 4 Likert-type scale. More specifically, it sums frequency and intensity in order to score symptoms on the three DSM-IV subscales of reexperiencing (Criterion B), avoidance and numbing (Criterion C), and hyperarousal (Criterion D). The CAPS was administered either in person or via telephone by licensed clinical psychologists, post-doctoral fellows, or by supervised senior doctoral students.

The *Timeline Follow-Back* (Sobell & Sobell, 1992) is a self-report measure used to assess alcohol use and provides data on maximum drinks, total drinks, drinking days, and heavy drinking days. It reminds users of the definition of one standard drink and is presented in a calendar format to allow users to report how many standard drinks were consumed during each day of tracking. The calendar helps identify certain events (e.g., holidays) to aid in recall of

drinks consumed. Five-day test-retest reliability was found to be strong, with coefficients ranging from 0.73-1.00.

The *Daily Behavioral Ratings* is a self-report form designed for the TMT program (DoD funded parent study) to track behaviors of interest over the course of a week. Behaviors included nightmares, flashbacks, sleep, social activities (both number of activities and minutes engaged in social activity), verbal rage episodes, physical rage episodes, overall anger, overall anxiety, smoking, exercise, and caffeine intake. Specifically, this study used the Daily Behavioral Ratings form to examine exercise, smoking, and caffeine.

#### 2.4.2 Combat Veterans with PTSD (PTSD+)

The *Structured Clinical Interview for DSM-IV, Clinician Version* (SCID-CV; First, Spitzer, Gibbon, & Williams, 1997) and the *Structured Clinical Interview for the DSM-IV Personality Disorders, Self-Report* (SCID-II-PQ; First, Gibbon, Spitzer, Williams, & Benjamin, 1997). This SCID is a semi-structured interview for Axis I DSM-IV-TR diagnoses and was used to assess for the presence or absence of Axis I disorders. Interrater reliability ranges from 0.57-1.0 for the SCID-CV (Zanarini et al., 2000) and 0.65-0.98 for the SCID-II-PQ (Maffei et al., 2997). Longitudinal assessments using multiple informants found support for superior validity of the SCID over other clinical interviews (Basco et al., 2000; Steiner, Tebes, Sledge, & Walker, 1995). Participants in the PTSD<sub>+</sub> group that met criteria for substance dependence, antisocial personality disorder, or psychotic disorders were excluded. Participants in the PTSD<sub>+</sub> group that had co-occurring depressive disorders, anxiety disorders, and personality disorders other than antisocial personality disorder qualified in order to be more representative of the high rates of

comorbidity across populations with PTSD (Keane & Kaloupek, 1997; Kessler et al., 2005). To be included, PTSD must have been the primary disorder for participants in the PTSD<sub>+</sub> group.

#### 2.4.3 Combat Veterans without PTSD (PTSD-)

The *Mini International Neuropsychiatric Interview*, *6.0 Version* (MINI; (Lecrubier et al., 1997; Sheehan et al., 1997), is a short structured diagnostic interview and was used to detect the presence of 17 Axis I disorders under the DSM-IV-TR, including mood disorders, anxiety disorders, and psychotic disorders. The MINI was chosen rather than the SCID-IV due to its shorter length of administration (approximately 15 minutes). It was utilized as a diagnostic interview to rule out any current diagnosis of PTSD, psychosis, active substance abuse or dependence in the PTSD- group. It has been shown to have good reliability with the SCID, with a sensitivity of 0.7 or higher and specificity of 0.85 or higher for all diagnoses (Sheehan et al., 1997).

#### 2.5 <u>Power and Sample Size Calculation</u>

G\*Power software version 3.1 (Faul, Erdfelder, Buchner, & Lang, 2009) was utilized to calculate sample size for a medium effect size (ES) value of 0.5. An alpha level of .05 and a power of 0.8 were used. For the between-groups analysis, 102 participants were required to reliably reject the null hypothesis. For the within-groups analysis, 28 participants were required to reliably reject the null hypothesis.

### 2.6 Data Analysis

Statistical analyses were conducted using IBM SPSS Statistics. Because data were nonparametric, the between-groups analyses were conducted using Mann-Whitney U tests. The within-groups analyses were conducted using Wilcoxon signed-rank tests and the Kruskal-Wallis H test.

#### **CHAPTER 3: RESULTS CHAPTER 3:**

#### 3.1 <u>Between Groups</u>

A t-test indicated there was not a significant difference in age between groups. Chi square tests indicated there were significant differences between groups on the variables of race/ethnicity, education, and TBI history (see Table 1). Significantly more participants with PTSD (35%) endorsed a history of TBI than participants without PTSD (12.5%). With regard to ethnicity, there was a higher percentage of PTSD+ participants (29.17% vs 8.33%) who identified as Hispanic and a higher percentage of PTSD- participants who identified as Asian (8.33% vs 1.67%) or African American (20.83% vs 7.5%). Higher percentages of participants with PTSD endorsed a high school diploma (18.33% vs 4.17%) or some college (58.33% vs 37.5%) as highest level of education obtained, while a higher percentage of participants without PTSD endorsed a bachelor's degree (29.17% vs 16.67%) or graduate degree (29.17% vs 6.67%) as the highest level of education obtained.

To address significant differences in demographics, 24 PTSD+ participants were matched on demographics with the PTSD- participants and then compared across health behaviors, utilizing Mann Whitney tests. A Bonferroni correction yielded a required alpha level of 0.0125. Using this correction factor, there were no significant differences in health behaviors between the matched groups. Because there were no significant differences when controlling for demographics, analyses were conducted using the entire available sample. When examining only those participants who endorsed a particular health behavior, results indicated that PTSD+

participants reported consuming an average of 13.50 drinks over a 30-day period, while PTSDparticipants reportedly consumed 19.50 drinks over 30 days. Over a 7-day period, PTSD+ participants reported consuming an average of 59 cigarettes, exercising for 190 minutes, and drinking 14 caffeinated beverages. PTSD- participants reported smoking an average of 32 cigarettes, exercising 285 minutes, and drinking 14 caffeinated beverages per week. Contrary to other studies, the hypothesis that PTSD is specifically related to higher levels of negative health behaviors was not supported in this sample.

	With PTSD $n = 120$	Without PTSD $n = 24$	Sig Different <.05	T tests/ Chi Square
Range	Age 21-71	25-54	Ν	t(142) = -0.648, n = 0.059
Mean	35.77	34.38		Mean of Both 35.53
	Sex/Gender			
Males	93.33%	100%	Ν	$\chi(1) = 1.694, p = 0.193$
Females	6.67%	0%		
	Race/Ethnicity			
Caucasian	56.67%	62.5%	Y	$\chi(4) = 11.554,$ p = 0.021
Hispanic	29.17%	8.33%		p 0.021
African American	7.5%	20.83%		
Asian	1.67%	8.33%		
Other	5%	0%		
	Branch			
Army	67.5%	54.17%	Ν	$\chi(4) = 4.021,$ n = 403
USMC	23.33%	37.5%		p = .403
Navy	3.33%	0%		
Air Force	4.17%	8.33%		
Contractor	1.67%	0%		
	Marital Status			chi square
Single	30.83%	25%	Ν	$\chi(4) = 3.182,$ p = .528
Married	47.5%	54.17%		×
Divorced	13.33%	20.83%		

# Table 3-1: Demographics

	With PTSD	Without PTSD	Sig	T tests/ Chi Square
	n = 120	n = 24	Different <.05	-
Widowed	0.83%	0%		
	Education			chi square
High School	18.33%	4.17%	Y	$\chi(3) =$ 15.482, $p = .001$
Some College	58.33%	37.5%		, <sub>F</sub>
Bachelor's Degree	16.67%	29.17%		
Master's/Doctoral	6.67%	29.17%		
	Traumatic Brain			
	Injury			
Yes	35%	12.5%	Y	$\chi(1) =$
No	64.17%	87.5%		4.812, <i>p</i> = .028
	Active Duty			
Yes	17.5%	29.17%	Ν	$\chi(1) =$ 1 738 $n = -187$
No	82.5%	70.83%		1.756, <i>p</i> = .167
	Service- Connected			
Percent Connected	Disability 57.5%	54.17%	Ν	$\chi(1) =$ 0.091, <i>p</i> = .763
Percent Connection	35.82%	27.92%	Ν	t(147) = -0.775, p = 0.440

Behavior	PTSD+ Median (Range)	Inter- quartile Range	PTSD- Median (range)	Inter- quartile Range	Sig Diff?	Mann-Whitney U
Alcohol (# drinks over 30 days)	13.50 (1-447) n = 83	22.0	19.50 (3-130) n = 18	32.25	N	u = -1.327, <i>p</i> = 0.185
Smoking (# cigarettes/week)	59.00 (1-280) n = 25	125.0	32.0 (4-54) n = 6	35.75	Ν	u = -1.726, <i>p</i> = 0.084
Exercise (# minutes/week)	190.00 (2- 1800) n = 36	252.5	285.00 (40-630) n = 19	360.0	Ν	u = -1.674, <i>p</i> = 0.094
Caffeine (# beverages/week)	14.00 (2-42) n = 48	17.0	14.00 n = 23	11.0	Ν	u = -0.658, <i>p</i> = 0.510

Table 3-2: Between-Groups Comparison of Health Behaviors

#### 3.2 Within Groups

Wilcoxon matched pairs signed rank tests were conducted to evaluate whether there were significant differences in health behaviors from pre- to post-treatment for the PTSD+ group. A Bonferroni correction yielded an alpha-level of 0.0125. When examining the PTSD+ participants who endorsed alcohol use, a significant difference was found in alcohol consumption (w = -6.088, p = 0.000), indicating participants significantly decreased alcohol intake from pretreatment (13.50 drinks over a 30 day period) to post-treatment (0 drinks over 30 day period). No other significant differences in health behaviors from pre- to post-treatment were found. When examining only those participants who endorsed a given behavior at post-assessment, participants reportedly consumed an average of 0 drinks. In addition, the PTSD+ group reported smoking 30 cigarettes (or one per day), exercising 150 minutes (approximately 21 minute per day), and drinking 9.5 caffeinated beverages per week (slightly over one per day).

A Kruskal-Wallis H test was conducted to determine if changes in health behaviors are related to change in PTSD symptoms. CAPS-IV scores were grouped based on the amount of change observed from pre- to post-treatment (low, medium, or high change). A significant difference was found in exercise (H(2) = 8.872; p = 0.012). Post hoc tests were conducted to determine at which level of change a significant difference was observed. However, when the corrected alpha-level of 0.0125 was applied to post-hoc tests, there were no significant differences found.

Behavior	Pre		Post			Wilcoxon
	Median	Inter-	Median	Inter-	Sig	Matched
	(Range)	quartile	(Range)	quartile	Diff?	Pairs Signed
		Range		Range		Rank Test
Alcohol (# drinks	13.50	22.0	0.00	5.0	Y	w = -6.088
over 30 days)	(1-447)	22.0	(0-140)	210	1	p = 0.000
						I
Smoking (#	59.00	125.0	30.00	88.0	Ν	w = -1.413.
cigarettes/week)	(1-280)		(0-280)			p = 0.158
Evereine (#	100.0	252 5	150.00	212.5	N	w = 0.202
Exercise (# minutes/week)	(2-1800)	232.3	(0.1080)	212.3	IN	w = -0.392, n = 0.695
minutes/week)	(2-1000)		(0-1000)			p = 0.075
Caffeine (#	14.0	17.0	9.50	16.25	Ν	w = -0.814,
beverages/week)	(2-42)		(0-42)			p = 0.416

Table 3-3: Within-Groups Comparison of Health Behaviors from Pre- to Post-treatment

Variable	Chi-Square	df	Sig	Sig diff?
Alcohol	0.980	2	0.613	N
Smoking	5.631	2	0.060	Ν
Exercise	8.874	2	0.012	Y
Caffeine	1.939	2	0.379	Ν

Table 3-4: Prediction of Health Behaviors Using CAPS Scores

### **CHAPTER 4: DISCUSSION**

This study did not find differences in levels of negative health behaviors when comparing combat veterans with PTSD to combat veterans without PTSD. This finding is in contrast to some other studies. Importantly, studies that found higher negative health behaviors among veterans with PTSD compared to veterans without PTSD did not exclude participants with substance use disorders (Beckham et al., 1995; Hoerster et al., 2012; Jacobson et al., 2008; Jakupcak et al., 2012), they included treatment-seeking and non-treatment-seeking veterans (Hoerster et al., 2012; Jacobson et al., 2008; Jakupcak et al., 2012; Jacobson et al., 2008; Jakupcak et al., 2012; Jacobson et al., 2008; Jakupcak et al., 2012), or they had a specific population of Vietnam veterans (Beckham et al., 1995; Beckham et al., 1998). Inclusion of participants with substance use disorder diagnoses may have led to an increased range of substance use. In addition, it may be that veterans who seek treatment for PTSD engage in negative health behaviors or other unhealthy coping mechanisms at a lower rate due to engaging in psychotherapy. Further, the studies do not specify whether veterans included in the studies experienced combat. The PTSD+ group in the present study included only veterans who served in OEF/OIF/OND, seeking treatment specifically for combat-related PTSD.

One reason for this finding may be due in part to the overall low level of negative health behaviors in this sample. More specifically, the U.S. Department of Health and Human Services (2015) indicates that low-risk drinking is equivalent to four or fewer alcoholic drinks per day and no more than 14 per week for men and one drink per day or seven per week for women. In this sample, 70.8% of the PTSD- group and 59.4% of the PTSD+ group at pretreatment endorsed some level of alcohol use. Of these, 94.4% of the PTSD- group and 82.6% of the PTSD+ group

reported alcohol consumption consistent with these guidelines at pretreatment. Similarly, the U.S. Department of Health and Human Services recommends that adults abstain from tobacco products including cigarettes (US Department of Health and Human Services, 2004). Again, the majority of the sample (75% of the PTSD- group and 53.1% of the PTSD+ group) reported they did not smoke cigarettes or consume tobacco products. Thus, this overall low level may have left little room for observable differences. The current recommendation for aerobic activity for adults is 150 minutes of moderate or 75 minutes of vigorous activity per week (American Heart Association, 2013); 79.2% of the PTSD- group and 50.0% of the PTSD+ group endorsed some level of exercise. Of these, 68.4% of the PTSD- group and 68.75% of the PTSD+ group reported aerobic exercise that meets or exceeds the current recommendation. Current guidelines suggest that adults should consume no more than 400 mg of caffeine per day (US Department of Health and Human Services, 2015). Though our study did not collect specific information regarding how much caffeine participants consumed per day, 4.2% of the PTSD- group reported no caffeine consumption, and 21.9% of the PTSD+ group reported no caffeine consumption at pretreatment. Given the high percentage of participants in both groups who reported low levels of negative health behaviors, and thus a low base rate, there may have been little chance for observable differences either between groups or from pre- to post-treatment.

A significant difference was found in alcohol use over time; specifically, alcohol use decreased at post-treatment. Existing literature has shown a relationship between PTSD improvement and substance use response in adults comorbid for PTSD and substance use disorder (Back, Brady, Sonne, & Verduin, 2006; Hien et al., 2009; Ouimette, Ahrens, Moos, & Finney, 1998; Sannibale et al., 2013). However, this study is the first to demonstrate a reduction

in subclinical alcohol use in combat veterans with PTSD using virtual-reality assisted exposure therapy, specifically. In addition, this study showed alcohol reduction in veterans regardless of the amount of change in PTSD symptoms. Thus, veterans with PTSD who have concerns about alcohol use (but are subclinical) may not require specific substance-use focused intervention in order to decrease alcohol use.

Within the PTSD+ group, 83.13% (n = 69) participants who engaged in alcohol use reported a decrease in drinking from pre- to post-treatment, while 6.02% (n = 5) reported no change, and 10.84% (n = 9) reported an increase in drinking at post-treatment. The average decrease was 11 drinks per month, while the average increase was 10 drinks per month (less the .5 drinks per day). Of particular note, 54 participants consumed alcohol at pre-treatment and reported no alcohol use at post-treatment. In addition, all participants who reported increases in their drinking nevertheless continued to consume alcohol within current recommended guidelines (US Department of Health and Human Services, 2004). Specifically, their drinking averaged to two or fewer drinks per day. Thus, increases in drinking do not appear to be clinically significant. All participants who reported increases in alcohol had reductions in their CAPS-IV score, with the average reduction of 48.22 points and a range of 15-75 points. Although not assessed, it may be possible that as veterans PTSD symptoms decreased, social activities that involved alcohol may have increased.

With regard to smoking, 62.5% (n = 10) reported a decrease, 12.5% (n = 2) reported no change, and 25% (n = 4) reported an increase. The average decrease was 22 cigarettes, or approximately one pack per week. Two individuals were successful in complete smoking cessation. The average increase was 19 cigarettes a week, or about one pack. These participants

had an average CAPS-IV reduction of 36.25 points. In fact, each of these participants had some reduction in CAPS-IV score (range 9-56). Again, if individuals increase social activities that include alcohol consumption, cigarette smoking may increase as well. However, recent studies indicate that individuals who are unable to quit but are successful in reducing their smoking (62.5%) may derive health benefits, such as improvement in cardiopulmonary function and lower risk of mortality (Begh, Lindson-Hawley, & Aveyard, 2015; Hatsukami, Henningfield, & Kotlyar, 2004), and that individuals who reduce their smoking are more likely to achieve total cessation (Begh et al., 2015). Although changes in smoking were not statistically significant in this study, there may be clinically significant health benefits for individuals who decreased their smoking.

With regard to exercise, 45.45% (n = 10) reported a decrease, 9.09% (n=2) reported no change, and 45.45% (n = 10) reported an increase. Decreases were, on average, 202.5 minutes per week, or approximately 30 minutes per day, while increases were an average of 175 minutes per week, or 25 minutes per day. Six of the ten participants who reported decreases in their exercise still endorsed some level of exercise over the course of a week. Recent studies indicate that individuals may derive physical and mental health benefits from exercise, even if it does not meet current recommendations (Buchman et al., 2012; Moore et al, 2012).

With regard to caffeine, 43.75% (n=14) reported a decrease, 3.13% (n=1) reported no change, and 53.13% (n=17) reported an increase. Among those who decreased their caffeine use, the average decrease was 10 drinks per week. For individuals who increased caffeine intake, the average increase was 5 drinks per week.

There has been concern about treating individuals with alcohol use and PTSD in an exposure paradigm due to fears that alcohol intake may increase to unhealthy levels (Najavits, 2006; van Minnen, Harned, Zoellner, & Mills, 2012). However, this study does not support such concerns for patients with subclinical alcohol use. In fact, exposure therapy may prove helpful for patients with PTSD who wish to decrease their alcohol intake. Given the results of this study, alcohol increase need not be a concern among clinicians who are trying to determine the appropriateness of exposure therapy.

Lack of significant change in other health behaviors may be due to a variety of factors. Although post-treatment behaviors were measured 17 weeks after pre-treatment behaviors, it may be that modification of health behaviors requires a longer duration. For example, it takes smokers an average of 8-11 attempts to permanently quit smoking (US Department of Health and Human Services, 2004). A recent study suggests that it takes an average of 66 days to learn a new habit (Lally, van Jaarsveld, Potts, & Wardle, 2010). It is possible that participants began changing behaviors close to the end of treatment, when PTSD symptoms were decreased, and assessments at a later duration would better capture this change. For smoking in particular, nicotine's addictive qualities may make it difficult to quit smoking within the 17-week period during which data were collected. There was a trend to smoke less (62.5%; just over a pack of cigarettes less per week), indicating that perhaps individuals had begun cutting down in an attempt to quit.

Although base rates of negative health behaviors in this sample were low, many of the combat veterans with PTSD reported that they previously engaged in higher levels of substance use and had decreased their use prior to participation in the program due to related negative

events (e.g., legal trouble, health problems). This type of qualitative information is not discussed in published studies that found negative health behavior differences, but may be of interest in this sample.

Overall, and probably most relevant, is the sample had a low number of participants who endorsed each health behavior. Of the PTSD- group, 25% did not endorse alcohol use, 75% did not endorse smoking, 20.8% did not endorse exercise, and 4.2% did not endorse caffeine use. In the PTSD+ group, 28.1% did not endorse alcohol use, 53.1% did not endorse smoking, 50% did not endorse exercise, and 20.9% did not endorse caffeine use. Given the overall sample size, this left relatively few participants who endorsed each behavior, with the exception of alcohol. Future research may wish to consider larger sample sizes for those who endorse a particular health behavior in order to track change over time.

Although results of extant literature indicate differences in health behaviors when comparing veterans with PTSD to veterans without PTSD, similar results were not found in this study. Differences among the studies may provide an explanation for this discrepancy. Jakupcak and colleagues (2010) found that veterans who screened positively on a self-report measure (PCL-M) for PTSD were more likely to report alcohol misuse than veterans who screened negatively for PTSD. Importantly, the current study used a semi-structured, clinicianadministered measure (CAPS-IV) to determine PTSD diagnosis, which may have led to a more stringent assessment as compared to utilizing a screening tool such as the PCL-5. Finally, several studies found differences in number of smokers or amount smoked in Vietnam veterans with and without PTSD (Beckham et al, 1995; Beckham et al., 1997; Koenen, Stellman, Sommer, & Stellman, 2008). Of note, smoking was more common throughout the United States in the

Vietnam era than today (Center for Disease Control, 2013), so these discrepant findings may be in part due to a cohort effect.

This study had strengths. It examined subclinical alcohol use in veterans with PTSD. Previous studies have focused on substance use disorders, so relatively little is known about subclinical alcohol use and PTSD. In addition, participants in the study were treated using exposure therapy, which is one of two empirically supported treatments for PTSD. Other studies investigating health behaviors and PTSD have used nonspecific CBT-based interventions. Our population was a mix of active duty military and veterans; thus, results likely generalize to both groups.

This study had limitations. There was a difference in sample size between the PTSD+ and PTSD- groups, particularly for alcohol consumption. Although the Mann-Whitney U test is robust to unequal sample sizes, future research should aim for less discrepancy in sample sizes between groups.

When using self-report data, validity must be considered. Future research may wish to incorporate technology such as activity trackers, heart-rate monitors, or electronic diaries in order to potentially increase reliability of health data. Finally, levels of health behaviors were not standardized. Different brands of cigarettes contain differing amounts of nicotine (Goniewicz, Kuma, Gawron, Knysak, & Kosmider, 2013; Jarvik et al., 2000), and the amount of nicotine a smoker absorbs differs based on individual characteristics, such as puff volume, depth of inhalation, and genetics (Farsalinos et al., 2015). Participants did not differentiate among aerobic, anaerobic, and resistance training in their reports, yet most research regarding exercise and mental health has focused on cardio-based aerobic activity (Josefsson, Lindwall, & Archer,

2014; Weinstein, Koehmstedt, & Kop, 2017). Caffeine was measured by asking participants to report the number of caffeinated beverages they consumed daily. Caffeine levels are not standardized; thus, it was not possible to determine the exact amount of caffeine participants consumed. Thus, participants with similar amounts of negative health behaviors could have varied in negative health behavior "dosage." Future research may wish to gather more detail regarding these variables in order to better account for differences in health behavior levels across participants.

Overall, results of the study indicate that the majority of participants with PTSD decrease their alcohol consumption after comprehensive treatment for PTSD, regardless of level of PTSD symptomatology. This suggests that participants with PTSD with concerns about alcohol use (but are subclinical) may successfully reduce alcohol consumption without specific substance-use focused intervention. This is in direct contradiction to those who express concerns regarding iatrogenic effects of exposure therapy. Likewise, other negative health behaviors did not increase as a result of treatment.

# **APPENDIX A: IRB LETTER**



University of Central Florida Institutional Review Board Office of Research & Commercialization 12201 Research Parkway, Suite 501 Orlando, Florida 32826-3246 Telephone: 407-823-2901 or 407-882-2276 www.research.ucf.edu/compliance/irb.html

### **Approval of Human Research**

From:	<b>UCF Institutional Review Board</b>
	#1 FWA00000351, IRB00001138

To: Deborah Casamassa Beidel

Date: July 21, 2016

Dear Researcher:

On 07/20/2016 the IRB approved the following human participant research until 07/19/2017 inclusive:

Type of Review:	Submission Response for IRB Continuing Review Application Full Board Review
Project Title:	Trauma Management Therapy for OEF and OIF Combat
·	Veterans
Investigator:	Deborah Casamassa Beidel
IRB Number:	SBE-10-07066
Funding Agency:	DOD/Army
Grant Title:	
Research ID:	1048785

The scientific merit of the research was considered during the IRB review. The Continuing Review Application must be submitted 30days prior to the expiration date for studies that were previously expedited, and 60 days prior to the expiration date for research that was previously reviewed at a convened meeting. Do not make changes to the study (i.e., protocol, methodology, consent form, personnel, site, etc.) before obtaining IRB approval. A Modification Form **cannot** be used to extend the approval period of a study. All forms may be completed and submitted online at <a href="https://iris.research.ucf.edu">https://iris.research.ucf.edu</a>.

If continuing review approval is not granted before the expiration date of 07/19/2017, approval of this research expires on that date. When you have completed your research, please submit a Study Closure request in iRIS so that IRB records will be accurate.

All data, including signed consent forms if applicable, must be retained and secured per protocol for a minimum of five years (six if HIPAA applies) past the completion of this research. Any links to the identification of participants should be maintained and secured per protocol. Additional requirements may be imposed by your funding agency,

your department, or other entities. Access to data is limited to authorized individuals listed as key study personnel.

In the conduct of this research, you are responsible to follow the requirements of the <u>Investigator Manual</u>.

On behalf of Sophia Dziegielewski, Ph.D., L.C.S.W., UCF IRB Chair, this letter is signed by:



Signature applied by Patria Davis on 07/21/2016 12:24:40 PM EDT

IRB Coordinator

## **APPENDIX B: IRB LETTER**



University of Central Florida Institutional Review Board Office of Research & Commercialization 12201 Research Parkway, Suite 501 Orlando, Florida 32826-3246 Telephone: 407-823-2901 or 407-882-2276 www.research.ucf.edu/compliance/irb.html

### **Approval of Human Research**

From: UCF Institutional Review Board #1 FWA00000351, IRB00001138

To: Michael A. Gramlich and Co-PI: Sandra M. Neer

Date: September 23, 2015

Dear Researcher:

On 09/23/2015, the IRB approved the following human participant research until 09/22/2016 inclusive:

Type of Review:	UCF Initial Review Submission Form
Project Title:	Posttraumatic Stress Disorder or Combat Experience? A
	Functional Near-infrared Spectroscopy Study of Trauma-related
	Olfactory and Auditory Cues
Investigator:	Michael A Gramlich
IRB Number:	SBE-15-11605
Funding Agency:	
Grant Title:	
Research ID:	N/A

The scientific merit of the research was considered during the IRB review. The Continuing Review Application must be submitted 30days prior to the expiration date for studies that were previously expedited, and 60 days prior to the expiration date for research that was previously reviewed at a convened meeting. Do not make changes to the study (i.e., protocol, methodology, consent form, personnel, site, etc.) before obtaining IRB approval. A Modification Form **cannot** be used to extend the approval period of a study. All forms may be completed and submitted online at https://iris.research.ucf.edu.

If continuing review approval is not granted before the expiration date of 09/22/2016, approval of this research expires on that date. When you have completed your research, please submit a Study Closure request in iRIS so that IRB records will be accurate.

Use of the approved, stamped consent document(s) is required. The new form supersedes all previous

versions, which are now invalid for further use. Only approved investigators (or other approved key study personnel) may solicit consent for research participation. Participants or their representatives must receive a signed and dated copy of the consent form(s).

All data, including signed consent forms if applicable, must be retained and secured per protocol for a minimum of five years (six if HIPAA applies) past the completion of this research. Any links to the identification of participants should be maintained and secured per protocol. Additional requirements may be imposed by your funding agency, your department, or other entities. Access to data is limited to authorized individuals listed as key study personnel.

In the conduct of this research, you are responsible to follow the requirements of the Investigator Manual.

On behalf of Sophia Dziegielewski, Ph.D., L.C.S.W., UCF IRB Chair, this letter is signed by:

Joanne muratori

Signature applied by Joanne Muratori on 09/23/2015 03:28:15 PM EDT IRB

Manager.

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