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Predicting dialectic behavioral treatment outcomes in veterans at high risk for suicide

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Abstract

Numerous studies have shown that veterans are at higher risk for suicide compared to the U.S. general population. Despite significant effort, awareness amongst clinicians and policymakers, these rates continue to increase. Dialectical Behavioral Therapy has shown great success in treating suicidality and emotional dysregulation due to mental illness such as Borderline Personality Disorder, yet has never been studied in the veteran population. The initial study found that veterans responded equally to DBT and TAU. This study looked at what clinical and demographic characteristics could predict DBT treatment success. Veterans who identified as women, with higher education, and more suicide attempts predictively found that DBT reduced their anxiety, and veterans who experienced greater combat exposure saw a greater reduction in depression symptoms post DBT.

Keywords: high risk suicide, veterans, dialectical behavioral therapy, DBT, treatment efficacy, predicting treatment success, treatment outcome

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CHAPTER I

Introduction

Suicide is an epidemic in the Unites States with over 40,000 Americans dying by suicide each year, about 13 per 100,000, and 836,000 reported attempts in emergency rooms (Kochanek, Murphy, Xu, & Tejada-Vera, 2014). Since 1999, completed suicides have increased 24% showing that this public health crisis is growing (Curtin, Warner, & Hedegaard, 2014). In the veteran population, these numbers are even higher with 35.3 per 100,000 veterans dying by suicide (Department of Defense, 2015) comprising 18% of all those who die by suicide (Department of Veterans Affairs, 2016).

Risk factors for suicide attempts are known to include demographics such age, race, previous attempts, and psychiatric vulnerabilities (Borges, Angst, Nock, Ruscio, & Kessler, 2008; Brown, Beck, Steer, & Grisham, 2000; Bryan, Bryan, Ray-Sannerud, Etienne, & Morrow, 2014; Fowler, 2012). For veterans and active duty military, risks also include psychosocial stressors, military sexual trauma, pre-military sexual trauma, and childhood sexual abuse (Bryan, Bryan, & Clemans, 2015; Kochanski-Ruscio, Carreno-Ponce, Deyoung, Grammer, & Ghahramanlou-Holloway, 2014). Mental illness is also implicated in suicidal ideation with 80% of those who attempt having a previous diagnosable mental illness (Nock, Hwang, Sampson, & Kessler, 2010). A recent longitudinal study determined that 20.3% of active and 42.4% of reserve component soldiers required treatment for their mental health (Milliken, Auchterlonie, & Hoge, 2007). Specifically, diagnoses associated with impulse regulation deficits in the amygdala (Hazlett, et al., 2016) including borderline personality disorders, mood disorders, substance use disorders, and anxiety disorders are connected to increased suicidal ideation, and are implicated

in higher rates of suicide attempts in civilian and military populations (Ho Choi, et al., 2013; Miranda, et al., 2008; Nock, et al., 2010).

Mental illness itself and suicidal ideation and attempts are far from predictive of suicide attempts, making clinical assessment and treatment challenging (Fowler, 2012; Borges, et al., 2008). With an increased awareness of this growing epidemic, particularly in the veteran population, there is a call for evaluating variations in treatment response. Understanding what prognostic factors influence or predict successful treatment for clients may lead to more individualized treatment and better outcomes, particularly a reduction in completed suicides.

In response to this threat, the US Department of Veterans Affairs organized a literature review meta-analysis of suicide prevention knowledge utilizing a panel of suicide prevention experts. The number of and generalizability of randomized control trials (RCTs) for interventions in suicidal events were shown to be limited, particularly in the veteran population. In this study, 20 RCTs post-suicide were assessed. There were only 3 RCT intervention studies included, and the only RCT evaluating DBT in veterans focused on 20 women with Borderline Personality Disorder diagnoses (Koons, et al., 2001). Moreover, psychosocial interventions were only found to be minimally helpful in suicide prevention. The biggest consensus is that there is a dirth in knowledge. More quality RCTs are needed for mental health treatment for veterans, particularly focused on suicide prevention.

CHAPTER II

Literature Review

Dialectical Behavioral Therapy

Dialectical Behavioral Therapy (DBT) has been repeatedly studied, and is the gold-standard for reducing suicidality in borderline personality disorder (Linehan, Armstrong, Suarez, Allmon, & Heard, 1991) compared with treatment as usual (TAU) in randomized control trials (Linehan, et al., 2006; Links, Ross, & Gunderson, 2015). There is also growing evidence that it is an effective treatment transdiagnostically (Neacsiu, Eberle, Kramer, Wiesmann, & Linehan, 2014) and with comorbid disorders including treatment of Axis I disorders, depression, anxiety (Harned, et al., 2008), and substance use disorders (Linehan, et al., 2002), PTSD (Polusny, Ries, Schultz, Calhoun, Clemensen, & Johnsen, 2008), and in inpatient settings (Bohus, et al., 2004). Yet in the veteran population, DBT RCTS have only been studied in small, targeted, sample groups (Koons, et al., 2001). Additionally, for many reasons, such as high clinician utilization (Goodman et al., 2016), DBT is also known to be very expensive (ZZZ). Moreover, until this study, few RCTs have evaluated the efficacy of DBT in the veteran population, nor a population consisting of mostly men of color.

DBT vs. TAU

In the parent study of this research published by Goodman, et al. (2016), veterans at high-risk for suicide were organized into two treatment groups, DBT and TAU, and efficacy of the different treatment modalities was assessed. Although DBT has expounding literature showing its efficacy, no significant differences were found between the DBT and the TAU groups. Both treatment modalities showed significant improvement in suicidal ideation, depression, and anxiety at 3 months and at after completion of treatment at 6 months. Moreover, there were no

differences between groups in suicide attempts or in hospitalizations, although DBT clients utilized a greater number of services.

As both DBT and TAU groups both showed improvement, the next logical question is why some client's improved, and some did not. What demographic, psychosocial characteristics, and life experiences can better predict which clients will be more successful in certain treatments. By identifying these variables, clinicians may be better able to develop individualized treatment plans and thus decrease suicidality. In particular, individual characteristics should better predict what clients may benefit most from DBT.

Clinical Relevance

It is clear that high-risk for suicide veterans require better tailored treatment, focused on their specific population needs. Identifying what unique treatment each individual veteran will respond best to will literally save lives. By understanding differences in treatment response clinicians can differentiate what client characteristics are predictive of better outcomes, allowing them to more quickly and effectively reduce the severity of suicidal behaviors and supporting those at higher risk for another suicide attempt. Moreover, if we know which veterans will do better in DBT on intake, and who may do better in other models, clinicians can offer more tailored treatment for each individual client, reduce the impact on clinicians that high utilization of their care can cause such as burnout, and reduce the overall cost of running DBT for those who would benefit from other programs. A transdiagnostic evaluation is important in generalizing for clinical utility, and is the current trend of research looking at "unified treatment" as recommended by NIMH (Barlow, 2004). Targeted treatment on intake would allow clinicians to have better outcomes for more veterans, and to identify when treatment is not working early on.

Treatment Variables

  Demographics. Demographics in predicting treatment outcomes have been mixed. Meta-analysis of anxiety disorders found that results were inconsistent, there were no predictive demographic factors across the board, which was partially associated with issues in study reliability and validity (Schneider, Arch, & Wolitzky-Taylor, 2015). Some studies have evidence that gender correlates to more positive outcome (Green, et al., 2015; Huibers, Cohen, Lemmens, & Arntz, 2015) while some show that identifying as a woman is associated with more anxiety symptoms and non-suicidal self injurious (NSSI) behavior (Bresin, & Schoenleber, 2015). For DBT, most RCTs were in sample of only women. Given that the veteran population consists of more men (Department of Veterans Affairs, 2015), and interaction between groups in the parent study were insignificant, it is likely this will not be a predictive factor in this study, or that we will not have enough of a balanced sample to generalize.

  Additionally, younger age of first attempt in veterans is associated with multiple attempts (Bryan, Rudd, & Wertenberger, 2016) which may be associated with more severe clinical pictures (Ho Choi, et al., 2013). This is consistent in treatment outcome studies where older age is associated with better outcome in CBT (O'Keeffe, Conway, & McGuire, 2016), as more severe clinical presentations can be subject to greater improvement.

  Symptomology. Initial severity of symptoms of depression, anxiety, and PTSD tend to respond better to treatment (Crits-Christoph, et al., 2001; Green, et al., 2015; Huibers, Cohen, Lemmens, & Arntz, 2015; van den Berg, et al., 2016) suggesting that is an important moderator of success. Baseline depression has been shown to be a treatment moderator in RCT's for Cognitive Behavioral Therapy (CBT) in at least one significant meta-analysis (Weitz, et al., 2015). These researchers hypothesize that veterans who responded to treatment will have higher

initial baseline symptom scores on the Beck Anxiety (BAI) and Beck Depression (BDI) scales. There is also building evidence that early treatment response is predictive of long-term treatment outcomes, although most studies focus on depression and anxiety (Crits-Christoph, et al., 2001; Delgadillo, et al., 2014; Lambert, Hansen, & Finch, 2001).

Psychosocial. Psychosocial experiences have an impact on both increased symptomology as well as treatment response. More severe suicidality, such as multiple suicide attempts has been associated, although unpredictably, with chronic or multiple psychosocial stressors (Bryan, Clemans, Leeson, & Rudd, 2015). Kochanski-Ruscio, et al. (2014) looked at psychosocial and clinical differences in veterans and found that there are clinically meaningful differences between those who have single and multiple attempts, diagnosis and childhood sexual abuse being two significant factors. Military sexual trauma (MST) and pre-military (lifetime) sexual trauma have shown to be a risk factor in suicidality as well (Bryan, Bryan, & Clemans, 2015). Patients were given both Combat Exposure Scale (CES; Keane et al., 1989), and the Childhood Trauma Questionnaire (CTQ; Bernstein & Fink, 1998). It is hypothesized that greater scores on these scales will moderate treatment outcomes.

Biases and Assumptions in the Previous Literature

The trend towards behavioral-based treatment seems both based in empirical literature, but also driven by insurance industry's limiting of the timeframe of therapy visits. This leads to problem-solving models, more so than exploration of the etiology of functioning over time. That said, DBT has been shown to be costly, at least in part due to an increase in use of clinical time (Goodman, et al., 2016) which has implications in both fiscal and clinician burnout.

CHAPTER III

Methods

Participants

This study included 29 veterans between 21-55 years old (*M age* = 37.21, SD= 11.39) who were receiving mental health services and were in a trial treatment program at the James J. Peter Veterans Administration Medical Center (JJPVA) in the Bronx, NY. This dataset was taken from a larger, completed RCT studying suicide risk factors transdiagnostically from January 2010 to December 2014. Veterans who met the criteria for "high-risk for suicide" status, were given either DBT or TAU for 6 months. High risk status was determined if any of the following criteria were met: 1) The veteran reported chronic suicidal ideation for at least a 3-month period, 2) was recently psychiatrically hospitalized due to suicidal ideation or a recent suicide attempt, or 3) was on the JJPVA list of "high risk" veterans the hospital suicide prevention coordinator (SPC) maintains. Exclusion criteria included having any type of DSM diagnosed psychotic disorder or history of or current organic brain disorder causing clinical impairment, including TBI. Access to stable housing, current or previous substance use, and current medication regimen were not grounds for disclusion. All participants were given written informed consent which was approved by the JJPVA Medical Center Institutional Review Board.

DBT Treatment

Participants were randomly placed by a computer program into DBT or TAU groups for 6 months of treatment. Veterans in the DBT group participated in a 90 minute weekly skills group, a 50-60 minute weekly individual therapy sessions, and were offered telephone coaching as needed. Therapists were all experienced clinicians who received a 10-day intensive DBT training and weekly consultation for the program. All therapists were rated for adherence to the

DBT program through videotaped sessions by Dr. Linehan's research group (http://www.linehaninstitute.org/). For more information, complete details of the study have been published elsewhere (Goodman, et al., 2016).

Measures

All veterans were given extensive intake protocol beginning with demographic information. Participants were given the Structured Clinical Interview for DSM-IV Axis I Disorders (SCID-IV; First, Spitzer, & Gibbon, 1996), Structured Interview for DSM-IV Personality Disorders (SIDP-IV; Pfohl, Blum, & Zimmerman, 1997), and the Clinician-Administered PTSD Scale for DSM-IV (CAPS; Blake et al., 1995). In addition, a full history of suicidal events from ideation to attempts was taken utilizing the Columbia–Suicide Severity Rating Scale (C-SSRS; Posner, et al., 2011). Psychosocial military experiences were reported through the Combat Exposure Scale (CES; Keane et al., 1989). Empirically validated self- report diagnostic measures including the Beck Anxiety Inventory (BAI; Beck, Epstein, Brown, & Steer, 1988) and the Beck Depression Inventory (BDI; Beck, Ward, Mendelson, Mock, & Erbaugh, 1961) were administered on intake and at completion of treatment at 6 months to determine baseline symptom severity and to identify symptom change over treatment. The Beck self-report inventories have been studied repeatedly and found to be both valid and reliable (Fydrich, Dowdall, & Chambless, 1992).

Variable Selection

The BAI and BDI were selected as dependent variables to measure severity of both depression and anxiety symptoms. Continuous change scores from baseline to 6 months were selected as the primary outcome measures for two separate regression models predicting treatment success. BAI and BDI were selected due to their proven validity and reliability

(Fydrich, Dowdall, & Chambless, 1992; Sprinkle, et al., 2002). Pearson's correlations were run

for BAI and BDI change scores across each variable both within treatment groups, and then

across treatment groups to ensure there was no treatment-specific change score included. The

first of this (Table 1) showed no correlations between change score and treatment group,

confirming the results of Goodman et al. (2016).

Table 1 Pearson's Correlations *Treatment Code Using* *Change Scores from 0-6m*		BAI	BDI
	Pearson Correlation	0.027	-0.225
	Sig. (2-tailed)	0.855	0.133
Treatment Code	N	50	46

Demographic factors were considered, including: age, gender, race, education, and

marital status. Additionally, military duration, number of suicide attempts, number of

hospitalizations for suicidality, and combat exposure were assessed. Although BDI change

scores were correlated with reduction in BAI and BAI change scores, we felt that including

treatment response in our regression model was not helpful in identifying on intake who will best

benefit from DBT, and thus was not included.

The primary analysis evaluated whether BAI and BDI change scores in veterans

receiving DBT could be predicted by individual clinical and personal characteristics.

Correlations were ran for change scores and the measures collected, and those which were

significant and clinically relevant were included. Two regression models were run, one for BAI

and one for BDI with the change score for each as a continuous dependent outcome variable.

Independent predictor variables included were: age, education, number of suicide attempts,

baseline anxiety or depression score, and combat exposure scale.

Table 2 Frequency Chart *Demographic and Clinical Characteristics*			
		Frequency	Percent
Sex	Female	8	27.6
	Male	21	72.4
	Total	29	100
Education	High School or less	7	24.1
	HS - BA (12-16yrs)	21	72.4
	Graduate Training +	1	3.4
	Total	29	100
Race	White	4	13.8
	Black	7	24.1
	Hispanic	15	51.7
	Mixed Race	3	10.3
	Total	29	100
Marital Status	Married	2	6.9
	Separated	3	10.3
	Divorced	12	41.4
	Single	12	41.4
	Total	29	100
Employment	Employed	7	24.1
	Unemployed	22	75.9
	Total	29	100
Current Mental Health Diagnosis	Substance Use	17	58.6
	Depression	18	62.1
	Borderline PD	15	51.7
	PTSD	15	51.7
	Anxiety	5	17.2
	Bipolar	2	6.9

CHAPTER IV

Results

29 veterans completed 6 months of treatment (*M*age= 37.21, 21 men). Clinical and demographic characteristics can be found in Table 2. The sample racially identified as 51.7% Hispanic, 24.1% Black, 13.8 % White, and 10.2% mixed/ multiple races. Diagnostically, results showed participants met criteria for mental health disorders, including: substance use 58.6%, depression 62.1%, post-traumatic stress 51.7%, anxiety 17.2%, and bipolar 6.9%, in addition to borderline personality disorder 51.7%. History of suicide attempts (*Mmd* = 2.41 attempts, SD 4.85) and individual descriptive statistics can be found in table 3, including participant's military duration which ranged from 1- 20 years (*Mmd* = 5.41 years, SD 4.20).

Table 3 Descriptive Statistics *Individual Characteristics*					
	N	Minimum	Maximum	Mean	SD
Age	29	21	55	37.21	11.39
Suicide Attempts	29	0	25	2.41	4.85
Combat Exposure	27	0	31	8.33	9.73
Military Duration	27	1	20	5.40	4.20

BAI Model. The BAI Model (table 4) was highly predictive of who responded best to DBT. Veterans at high risk for suicide were predictively more likely to see a reduction in symptoms of anxiety with DBT treatment when they presented with previous suicide attempts, and a higher level of education. At the trend level, those with higher baseline anxiety were correlated with but not predictive of better treatment response. This was included to control for interaction effects.

Table 4 Regression Analysis
Dependent Variable Beck's Anxiety Change Score from 0-6 Months

Model	Unstandardized Coeff		Standardized Coeff	t	Sig.	95.0% Confidence Interval for B		Collinearity Statistics	
	B	Std. Error	Beta			Lower Bound	Upper Bound	Tolerance	VIF
(Constant)	-11.713	7.756		-1.51	0.147	-27.892	4.465		
Age	0.353	0.162	0.357	2.174	0.042	0.014	0.692	0.518	1.932
Sex	-9.849	3.559	-0.388	-2.767	0.012	-17.274	-2.424	0.708	1.412
Education Level	8.17	2.873	0.365	2.843	0.01	2.176	14.164	0.845	1.183
# Suicide Attempts	0.705	0.302	0.311	2.338	0.03	0.076	1.334	0.784	1.276
Combat Exposure	0.148	0.16	0.127	0.927	0.365	-0.185	0.482	0.74	1.352
Baseline BAI	0.254	0.117	0.302	2.184	0.041	0.011	0.498	0.728	1.373

Suicide attempts as assessed in the C-SSRS were highly predictive in the efficacy of DBT reducing symptoms of anxiety. Attempts were included as a continuous variable, and ranged from 0 attempts (24.1%) to 25+ attempts (3.4%). For every point of symptom reduction in the BAI scale, suicide attempts went up .705 points a = 0.03. This follows what previous RCTs have shown, that DBT is highly recommended for clients with significant suicide event histories. Level of education was also a significant predictor of DBT outcomes. The more education veterans had, the better their symptoms of anxiety responded to DBT by 8.17 points, a = 0.01.

Baseline anxiety, although significantly correlated (P = .458, a = 0.019) to BAI change score in the DBT subgroup, was not predictive of reduction in BAI symptoms. Age was also correlated with BAI change scores in the DBT subgroup (P = .422, a = 3 CORRELATION.RERUN.042717), so was included as a control, although was also not predictive of outcome. Combat exposure (CES), was not correlated with BAI change score.

BDI Model. Interestingly, the BDI model (table 5) was only minimally predictive of treatment efficacy. CES was the only predictive variable for reduction in symptom.

Table 5 Regression Analysis Dependent Variable Beck's Depression Change Score from 0-6 Months									
	Unstandardized Coefficients		Standardized Coefficients			95.0% Confidence Interval for B		Collinearity Statistics	
	B	Std. Error	Beta	t	Sig.	Lower Bound	Upper Bound	Tolerance	VIF
(Constant)	-10.899	13.547		-0.804	0.433	-39.618	17.821		
Age	0.32	0.262	0.335	1.225	0.238	-0.234	0.875	0.579	1.727
Sex	-6.783	7.126	-0.277	-0.952	0.355	-21.89	8.324	0.512	1.953
Education Level	3.191	4.626	0.151	0.69	0.5	-6.615	12.998	0.911	1.097
# Suicide Attempts	0.012	1.26	0.003	0.009	0.993	-2.659	2.682	0.593	1.685
Combat Exposure	0.607	0.264	0.547	2.303	0.035	0.048	1.166	0.771	1.297
Baseline BDI	0.218	0.2	0.253	1.091	0.291	-0.205	0.641	0.811	1.233

This is particularly interesting, as CES trended towards correlation in BDI change score, and was included due to clinical insight and literature review evidence. Age was correlated with BAI change scores in the DBT subgroup (P = .454, a = .020) but not predictive. Neither age nor number of suicide attempts were correlated to nor predictive of BDI outcomes.

CHAPTER V

Discussion

This is the first transdiagnostic DBT RCT evaluating treatment response over 6 months of DBT treatment in a high-risk for suicide veteran population, and to consist of mostly men. Our study predicted DBT treatment outcomes, specifically identifying individual characteristics at baseline which determined the most significant reduction in symptoms of anxiety and but not depression. As theorized, greater suicidality, specifically number of suicide attempts were highly predictive of anxiety symptoms reduction (table 4). Veterans with a greater number of suicide attempts were most likely to benefit from DBT, confirming what other DBT RCTs have shown. This is likely due to DBTs focus on emotional regulation and distress tolerance, both of which are implicated in suicidal events, and in reducing anxiety symptoms. This follows the literature where those who are in greater distress, experiencing higher levels of anxiety are either more open to or are internalizing the skills of DBT differently. What was also interesting is that those with higher levels of education also saw a greater decrease in symptoms of anxiety. It may be that the structure of DBT programs makes more sense to or is more easily digested by those who have spent time in structured educational environments. It is also possible that there is overlap in the skills which are required for success in higher education and DBT skills.

We were surprised to find that a reduction in depression symptoms were really not predictable, nor were they correlated with most of the variables that the literature and clinical experience would suggest. This includes demographic data, baseline scores, or even suicidality, which was highly predictive in anxiety reduction and supported in previous literature. Only higher scores on the Combat Exposure Scale were predictive of reduction in symptoms of depression (table 5. This could represent that for those who have had significant combat

exposure which they are having a depressive reaction to, DBT tools can be very helpful, but that for veterans at high risk for suicide, more organic depression symptoms are not impacted by DBT. This may suggest that DBT is better at reducing symptoms of anxiety in particular. Curiously, CES scores did not predict changes in BAI, so this is depression symptom specific. Baseline BDI scores were neither correlated to nor predictive of reduction in depression symptoms, a surprising finding. One theory is that in the case of veterans the experiences they have, such as combat exposure are not necessarily organic in their expression so are less about learning how to regulate emotion to reduce depression, but are about facing moral injury. In this case, DBT is helping veterans to process their painful experiences, reducing symptoms, as opposed to learning better coping skills for managing dysregulation shown through suicide attempts. This is a theory because these findings are very unique in the literature.

Additionally, RCTs are well known for attrition, and a study of this length and size was not exempt from this. Originally there were 91 cases in the treatment study, 46 of which were in the DBT group. Of those, only 29 had BAI and 28 BDI scores at baseline and at 6 months. Sample sizes for scores in Beck Suicide and Hopelessness Scales were too low to justify inclusion in this study.

This sample consisted of mostly men, although only male and female were available selections of sex, as opposed to non-binary gender considerations. Although sex was correlated to treatment success in both anxiety and depression, which confirms a gendered response to DBT. Women are a smaller subset of this sample, so future studies with more data and thus greater power is needed to confirm this. Additionally, in this paper's discussion, the research term "Hispanic" is changed to Latinx to respect contemporary use of categorization.

It is also important to note the lens with which this research, and the secondary analysis have been run, and where this sample can be generalized to. In most studies evaluating efficacy of DBT, all if not most of the patients are women, and many are samples of white women. In a VA sample, the opposite is true, thus the racial makeup of the sample at baseline is quite different than previous studies. Veterans at the enlistment level also have notably different racial makeup than the American population. No correlation was found between change scores and racial identity, thus the variable was not included in the regression model. Yet, 75.8% of this sample identifies as Black or Latinx people of color, which may impact the generalizability while also giving us insight into a population that has not been studied in this context previously. This sample does lead to important clinical considerations of intersectional identities and their impact on mental health outcomes. By accident, this study is the first to look at DBT outcomes in a sample consisting primarily of men of color and may explain why, in the initial study, DBT was equally effective as TAU. Most DBT trial samples consist of women, and many times, white women. In future studies, evaluating racial and gender makeup would be highly beneficial in understanding and tailoring treatment and in generalizability of studies.

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Appendix A

Subcommittee Research Safety
Bronx VA Medical Center
Research & Development Program (151)
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APPROVAL - Continuing Review

Date: March 4, 2016
From: Ruth Walker, MBChB, Ph.D., Chairperson
Investigator: Marianne Goodman, M.D.
Protocol: Affective Startle Assessment in High Risk Suicidal Veterans
ID: 01388   Prom#: N/A   Protocol#: GOO-11-058

The following items were reviewed and approved at the 02/10/2016 meeting:
- Abstract (Protocol Summary) (01/11/2016)
- Annual Adverse Event Report Form (01/11/2016)
- Annual Enrollment Form (01/11/2016)
- Budget Page (01/11/2016)
- Conflict of Interest (01/11/2016)
- Consent Form (01/11/2016)
- Continuing Review (01/11/2016)
- HIPAA Authorization (VA form 10-0493) (01/11/2016)
- HIPAA Revocation of Authorization (VA form 10-101 (01/11/2016)
- Lay Research Summary (01/11/2016)
- Personnel Record (01/11/2016)
- Progress Report (01/11/2016)
- Research Protocol (01/11/2016)
- Signature Page(s) (01/11/2016)

The following additional items were received to address stipulations and are now approved:
- PI Annual Research Protocol Safety Update (01/11/2016)

Contingency resolved. No further issues. SRS approved.

The following other committee reviews are scheduled:
Institutional Review Board [01/05/2017]

Approval by each of the following is required prior to study continuation:
Institutional Review Board [Approval Granted 02/04/2016]
Research & Development Committee