## I. HHRF RESEARCH GRANT APPLICATION COVER LETTER

**Title of Project**: Examination of the effects of equine assisted activities on PTSD symptoms, quality of life and participation in combat veterans.

Submission Date: May 15, 2014

Principal Investigator Name and Title**:** Beth Lanning, PhD, MCHES. Associate Professor and Director Community Health Program, Baylor University.

Contract Person Name and Title:

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Primary focus area of the investigation (i.e. mental health, physical therapy, speech therapy, occupational therapy, education, recreation, the horse-human relationship): Mental health, the horse-human relationship, and education.

Years and Titles of past HHRF Funding Applications: none

**Safety and quality standards for EAA/T:**

Name(s) of personnel directly involved with any associated EAA/T:

**R.O.C.K. Georgetown, Texas & Courtney Cares- Texas A&M System College Station, Texas**

- Nancy Krenek, PT, PATH Certified Riding Instructor, PATH #12654

**Rainier Therapeutic Riding Facility, Yelm, Washington**

- Elisia Mutter, PATH Certified Riding Instructor, PATH # 5609720

**R.E.A.C.H Therapeutic Riding Facility, McGregor, Texas**

- Karen Fraser, PATH Certified Riding Instructor, PATH # 76891

**Horses Helping the Handicapped, Inc. (Triple H Equitherapy Center), Pipe Creek, Texas**

- Laura Berlin, PATH Certified Riding Instructor, PATH # 5206090

Are all listed personnel certified to provide the activities? Yes

Certifications through Professional Association of Therapeutic Horsemanship International.

**Site standards for EAA/T:**

Is the site providing EAA/T programming accredited to do so? Yes

Will others collaborate or consult with you on this project? Yes (If yes, list Individuals or Organizations collaborating on project)

R.O.C.K. PATH # 40603
Rainier Therapeutic Riding PATH # 81802
R.E.A.C.H. Therapeutic Riding (finishing accreditation through PATH)
Triple H Equitherapy Center PATH #21047
All four facilities are accredited through PATH International. Courtney Cares (Texas A&M Systems) is being directed by the ROCK director.

All letters stating agreement to collaborate on the project are attached.

**Brief description of project** (60 words or less): The purpose of the research project is to assess changes in PTSD symptoms, quality of life and participation of combat veteran who participate in equine assisted activities. The proposed study is a mixed-methods, waitlist-controlled, repeated measures trial of a standardized 8-week therapeutic riding intervention for combat veterans with PTSD. Behavioral changes will be assessed four times during the study.

Pilot Study Completed? Yes Completion Date: April 2011

Is project Institutional Review Board approved? Yes. IACUC approved, also. BAMC IRB approval pending (military).
Please attach a copy of the IRB application. Attached.

Start Date of Project: October 1, 2014 End Date of Project: December 31, 2015

Amount Requested from HHRF: $ 50,000.00

## II. SCIENTIFIC ABSTRACT

Empirical research supporting equine assisted activities and therapies (EAAT) as effective alternatives to traditional physical and psychological therapies is emerging but still in its infancy. Even more sparse are studies examining the therapeutic effects of EAAT for veterans with physical and/or mental wounds. The aim of the purposed study is to address the need for research in this area by examining the effects of EAA (e.g., therapeutic riding) as an intervention for combat veterans experiencing PTSD symptoms and impaired functioning. The secondary aim is to use the International Classification of Disability and Functioning (ICF) as a framework to investigate the relationships of PTSD symptoms, quality of life components and participation and how EAA may influence these variables. To achieve these aims, a randomized experimental trial will be conducted. Participants (veterans) will be assigned to an eight week EAA treatment group or a waitlist control group. After eight weeks, the control group participants will be assigned to a treatment group. Participants will complete assessments at baseline, mid-treatment, post-treatment and two-month follow-up. Additional assessments will be completed by a caregiver/spouse or physician pre and post treatment. Analysis of the data will help determine how EAA affect functional behaviors in veterans experiencing impairment.

## III. NEED/JUSTIFICATION

Posttraumatic Stress Disorder (PTSD) is one of the most prevalent anxiety disorders in the United States, effecting 6.8% of adult Americans (Kessler, Sonnega, Bromet, Hughes & Nelson, 1995). However, the prevalence of PTSD is much higher in combat veterans. According to the RAND Corporation, Center for Military Health Policy Research population-based study, the prevalence of PTSD among previously deployed Operation Enduring Freedom and Operation Iraqi Freedom (OEF, OIF) Afghanistan and Iraq service members is 13.8%, more than double the prevalence of non-military adults (Schell & Marshall, 2008). Many veterans returning from combat operations in Iraq and Afghanistan will experience significant symptoms of PTSD (Milliken, Auchterlonie, & Hoge, 2007) making this a high risk population. PTSD is linked to exposure of a traumatic event that involved the threat of injury or death. While there is no single test to diagnosis PTSD, diagnosis can be made on the presentation of specific symptoms such as reliving the event, avoidance and numbness or shutting down, loss of trust in humans and hyperarousal (American Psychiatric Association, 2013). In addition to the core symptoms of PTSD, related symptoms may include a variety of physical health problems including chronic pain, back problems, cardiovascular disease (Beckham et al., 1997; Asmundson, Coons, Taylor, & Katz, 2002) and overall disability. Therefore, finding affective treatments to address the spectrum of difficulties is critical to long term recovery.

One of the effects of PTSD currently receiving greater attention in the literature is the dynamic interplay of PTSD symptoms, functional impairment and a reduction in quality of life, specifically in veterans. In a recent review of literature on PTSD symptoms, Schmurr, Lunney, Bovin and Marx (2009) reported that while studies have been conducted on how PTSD symptoms affect all types of functioning including, social and interpersonal functioning; marital

functioning; parental and family functioning; and occupational functioning, there have been relatively few studies examining objective indicators of quality of life and PTSD.

Quality of life can be defined in several ways but it is generally accepted as "individuals' perception of their position in life in the context of the culture, the value system in which they live and in relations to their goals, expectations, standards and concerns" (WHOQOL Group, 1996, p. 5). PTSD has been associated with a general decline in quality of life among veterans and non-veterans, but most studies have focused on non-veterans (Schmurr et al., 2009). The need for more longitudinal research on the dynamic relationship between PTSD and quality of life in OEF/OIF veterans is needed for the development of more effective treatment plans.

Traditional therapy for PTSD has focused primarily on cognitive behavior therapy approaches, particularly exposure therapy and cognitive restructuring as well as eye movement desensitization and reprocessing (Sherman, 1998). Bradley, Green, Russ, Dutra and Westen (2005) conducted a meta-analysis of 26 studies utilizing psychotherapy for PTSD and found brief psychotherapy approaches to be effective in reducing PTSD symptoms. Although some of the studies included treatment outcome trials with combat veterans, the studies were not designed specifically for this population. Existing reports, specifically targeting veterans, have produced inconsistent findings on the effectiveness of combat-related PTSD treatment. Goodson et al. (2011) meta-analysis of 24 VA treatment studies for combat-related PTSD found overall moderate treatment effectiveness. The researchers concluded that even though veterans with combat-related PTSD are amenable to treatment interventions, veterans respond less well than do civilians in well-controlled clinical trials. Several possible explanations for this discrepancy have been suggested. The severity of the symptoms associated with combat-related PTSD may adversely affect the veterans' response to treatment (Durham, Allan, & Hackett, 1997; Westen &

Morrison, 2001; Durham et al., 2004); veterans with PTSD are more likely to present with multiple physical and psychiatric conditions, which may pose additional treatment challenges (Frueh, Turner, Beidel, Mirabella, & Jones, 1996); combat veterans may experience greater guilt and shame about their combat-related actions, making treatment more difficult (Foa & Meadows, 1997); and combat veterans have often been exposed to a greater number of traumas than have civilians with PTSD, so their symptoms may be more resistant to treatment. Furthermore, only a small number of soldiers returning from deployment who experience symptoms of PTSD seek mental health treatment making effective treatment even more difficult (Hoge, Auchterloinie & Milliken, 2006; Milliken, Auchterlonie & Hoge, 2007). In addition, an increasing number of veterans are turning to the private and community sectors for help outside traditional military services (Tanielian et al., 2008). With these challenges in mind, it is important to critically examine alternative treatments which may prove effective in treating combat-related PTSD and which prioritize improved quality of life as a treatment goal (Schnurr et al., 2009).

One alternative treatment/intervention showing promise is equine assisted activities (EAA) which includes therapeutic riding (TR). Therapeutic riding uses equine-assisted activities for the purpose of contributing positively to cognitive, physical, emotional and social well-being of people with disabilities ("PATHInt.org," 2012). While efficacy studies examining therapeutic riding as an intervention for children with disabilities have begun to emerge (e.g., Bass et al, 2009, Kern et al. 2011; Gabriels et al. 2012), little research exists on programs incorporating therapeutic riding to help combat veterans reintegrated into civilian life. To date, most findings, while positive, are anecdotal. Our pilot study (Lanning & Krenek, 2013) will hopefully begin to generate more interest in empirically evaluating the efficacy of TR for combat veterans. In our study, we examined the effects of TR on quality of life and depression symptom of combat

soldiers. Thirteen soldiers participated in twelve sessions of TR. A mixed-method research design incorporating both qualitative and quantitative data was used to assess changes in health domains associated with quality of life. Qualitative analysis of post intervention interviews provided emerging themes, which supported improved quality of life. Descriptive analysis of the quantitative data revealed changes in seven of the eight quality of life domains and a reduction in depression symptoms. While both statistical and clinical significant changes were noted, the lack of a control group prohibited further analysis. The current research proposal is designed to: build on information obtain from the pilot study, address gaps in the research especially in the areas of EAA, PTSD, functioning, and quality of life, and introduce the use of a participation based theoretical framework for planning EAA interventions.

## IV. RESEARCH NARRATIVE

### Innovation

The mix-method research design of our pilot study proved to be very beneficial in understanding changes in quality of life domains of the participants and will be utilized again in this study. Pilot study results revealed a greater increase in mental health domains than physical domains. Of special notice was the relatively steady nature of bodily pain yet an increase in overall mental health. In order to more fully understand the link between physical disability and mental disability in the combat veteran, the International Classification of Functioning, Disability and Health (ICF), adopted by the World Health Organization in 2001, will be used as the theoretical underpinning of the proposed study. The ICF model is a patient-centered evaluation tool, which provides an effective plan for evaluating an individual to determine a broad picture of an individual's strengths and challenges. This model helps clinicians and practitioners visualize the relationships between different components and thus aids in

organizing complex situations with multiple challenges in a more concise and novel way. The model helps the clinician shift the focus from the cause of impairment to the outcome. Further, the model includes social aspects of disability with environment as a contributing factor on the person's overall functioning (WHO, 2001).

Symptomology and impairments of PTSD are closely linked but may describe very distinct and different outcomes. Functional impairment is usually associated with social and occupational functioning. However, symptoms are not always evident and the relationship of the symptom to the impairment is not always transparent. In some situations, the symptoms may no longer cause functional impairment in all situations. For example, hypervigilence is extremely important on the combat field but it interferes with social interactions in civilian life (Rodriquez, Holowka, & Marx, 2012). Furthermore, depression is a comorbid in PTSD and can affect functioning as well as quality of life. In our pilot study, we examined the effect of EAA on depression and quality of life and found general trends in reduction of depression symptoms and the improvement in quality of life. Significant improvement was noted in quality of life domains, which corresponded to social functioning (e.g., Role-physical and Role-emotional). The veterans reported a significant reduction in functioning impairment caused by emotional factors. We will build on these findings in the proposed study. Special consideration will be given to how PTSD symptoms or symptom clusters affect different aspects of functioning and how the TR intervention influences these connections.

**Theory Constructs (See Proposed Theoretical Model in attachments)**

Quality of life

Quality of life typically refers to physical, mental, and social well-being or the degree to which a person experiences satisfaction with everyday activities (Gladis, Gosch, Dishuk, &

Critis-Christoph, 1999; Mendlowicz & Stein, 2000). Gladis et al. (1999) further divide the concept of quality of life into three components: social-material conditions, functioning (role performance), and satisfaction (well-being), all of which can be measured. The three component approach to defining quality of life will be used in the proposed study. (See Table 1 in attachments).

International Classification of Functioning, Disability and Health (ICF) Model

The ICF is a tool that can be used to classify health and related health domains. It shifts the focus from only considering the disability to including the social aspects of disability as well as contextual influences such as environment and personality. Further, it can be used as a tool to identify areas of impairment and influence, set goals, and structure interventions (Rauch, Cieza, & Stucki, 2008). The ICF components include:1) Body Function and Structures- the physiological functioning of the body systems, 2)Activities- execution of everyday activities, 3) Participation- involvement in everyday life situations, 4) Environment- the physical and social environment in which people live and function, 5) Personal factors- lifestyle, habits, education, social factors, life events, gender, ethnicity (WHO, 2003).

PTSD Symptoms

Posttraumatic stress disorder occurs as a result of exposure to a traumatic event and is best defined by the manifestation of symptoms or symptom clusters. The four diagnostic clusters are identified as re-experiencing, avoidance, negative cognition and mood and arousal (American Psychiatric Association, 2013). While researchers have begun to investigate how PTSD symptoms or symptom clusters affect different aspects of functioning, little research has explored the simultaneous relationship of these symptoms across all three quality of life

components (i.e., social-material, functioning, satisfaction) especially in combat veterans (Schnurr et al., 2009).

Equine Assisted Activities

Equine assisted activities are specific activities, which involve an equine, participant, volunteers and instructors and may include therapeutic riding, mounted or ground activities, grooming and stable management. These activities are designed to help " individuals with physical, mental and emotional challenges find strength and independence through the power of the horse" ("PATHIntl.org," 2013). Preliminary research findings support the association between EAAT interventions and positive behavioural outcomes including improved social functioning (Bass et al., 2009; Kern et al. 2011), self-esteem (Rothe, Vega, Torres, Soler, & Pazos, 2005) emotional regulation (Gabriels et al. 2012), social competence (Pendry and Roeter, 2012) and a decrease in depression symptoms (Bowers & MacDonald, 2001). Most studies regarding EAAT have included children and adolescents. Relatively few studies have examined the impact of EAAT on adult populations and, even fewer, have included veterans.

While our study will assess some of the same functional behaviors as previous studies (e.g., social functioning, emotional regulation, participation) it will differ in the approach. By utilizing the ICF framework, we will investigate how EAA appear to improve behaviors often exhibited by veterans with PTSD or PTSD symptoms, the relationship of PTSD symptoms to levels of functioning, quality of life components and improvement in participation.

**Research Question**

The main research question being proposed is how does engaging in equine assisted activities (therapeutic riding) affect functional impairment (e.g., anxiety, isolation, withdrawal from meaningful activities, poor communication skills) and quality of life in veterans with combat-

related PTSD/TBI, with a specific focus on social/life participation. In addition, we aim to answer the question of how change in specific types of PTSD symptoms relates to change in quality of life and functional impairment

**Hypotheses**

We hypothesize that veterans participating in TR will demonstrate an improvement in life satisfaction and participation and a reduction in PTSD symptoms. We theorize that one reason why TR leads to positive changes in behavior and a reduction in functional impairment for veterans with combat-related PTSD is that the partnership between the horse and the veteran provides a non-threating foundation for self-exploration and post-traumatic growth. This growth will most easily be documented by observing changes in specific behavioral outcomes and an assessment of overall quality of life and life satisfaction. Three hypotheses are proposed to guide the study and the data analysis.

*Hypothesis one:* Veterans participating in TR will report higher levels of life satisfaction than non-participants.

*Hypothesis two*: Veterans participating in TR will report lower levels of functional impairment than non-participants.

*Hypothesis three*: Changes in quality of life and PTSD symptoms will be sustained over time.

**Design**

The research design will be a mixed-method, waitlist-control, experiment, with repeated measures. Participants will be randomly assigned to a treatment group or a waitlist control group. Data will be collected at four time points: at baseline (pre-intervention), mid-intervention, post-intervention, and 2-month follow-up. All University Institutional Research Board and Animal Care and Use Committee approvals have been obtained. Military IRB approval is pending, but it is not necessary to continue the study. (See subsequent section on participants).

## Methods

### Participant

*Selection Criteria (Inclusion and Exclusion Criteria)*

The main inclusion and exclusion criteria are veterans who participated in any of the three Iraq and Afghanistan war missions (OEF- Operation Enduring Freedom, Operation Iraqi Freedom, OND- Operation New Dawn), diagnosed with PTSD or exhibiting PTSD symptoms, and have not participated in EAAT six months prior to the start of the study. (See Table 2 for a complete list of inclusion and exclusion criteria). Veterans will be recruited from resident military personnel within a 75-mile radius of each testing site including veterans from a military base and Veterans Health Care System (VA) Centers. Recruitment will occur through visits to the local army hospital and military base, word of mouth, and brochures handed out at local meetings for veterans. In addition, local congressmen, VA programs and VA counselors will be informed of this study. No veterans will be recruited directly through military publications or by assignment from their commander unless military IRB approval has been obtained.

*Sample Size*

Sample size was determined using a Monte Carlo study (Muthen & Muthen, 2002). Power analyses were run based on the parameters specified in Table 3 (in attachments). The main focus of the power analysis was the difference in means at the last time point. The effect size estimated was $d = 0.60$, which is similar to the effect size found in a recent study examining the effects of EAA with an at-risk population (Pendry & Roeter, 2013). Power charts for scenarios with and without missing data are given in Figures 1 and 2, which can be found in the attachments. Based on the results, we determined we need a sample size of 75 participants. The initial phase of this study, recruitment of 15 participants, has begun and is funded by another source. The current

proposal for funding will allow us to recruit the remaining 60 participants needed to complete the study.

Testing sites

Five therapeutic riding facilities will be utilized for this study: Ride On Center for Kids (R.O.C.K.), Georgetown, Texas; Riding Equines to Achieve Confidence and Health (R.E.A.C.H.), McGregor, Texas; Texas A&M Systems Courtney Grimshaw Fowler Equine Therapeutic Riding Center (Courtney Cares), College Station, Texas; Triple H Equitherapy Center, Pipe Creek, Texas; and Rainier Therapeutic Riding, Yelm, Washington. Four of the sites (R.O.C.K., Rainier TR, R.E.A.C.H., Triple H) are PATH Premier Accredited facilities, and one (Courtney Cares) is under the direction of the research director of R.O.C.K. All five sites have existing PATH Equine for Service Members programs and the staff is experienced with the veteran population. Five sites are needed to ensure adequate sample size for the study.

Measures

Both qualitative and quantitative assessments will be used to obtain information about behavioral outcomes. Post-intervention semi-structured questions will be used to gather qualitative feedback on behaviors, attitudes and level of life satisfaction. Several assessments will be used to gather quantitative information on PTSD symptoms, quality of life, functional impairment and participation. The relationships between quality of life components, PTSD symptom clusters and functioning is complex and not clearly defined (Schnurr et al., 2009) therefore, multiple assessments from various perspectives will be needed to understand the shared and unique features of each behavior and relationship. Instruments were chosen based on the following criteria: validated and reliable for testing the behaviors outlined in this study,

linked to the ICF classification, and were relatively short and easy to complete by the participant, family member, volunteer or instructor.

*PTSD Checklist—5*

The PCL-5 is a 20-item measure designed to assess PTSD symptom severity. The PCL-5 is a recent revision of the commonly used PCL (DSM-IV) developed to better reflect the changes in PTSD as outlined in the DSM-5. These revision included changes in the existing symptoms of PTSD and the addition of three new symptoms, which resulted in increasing the number of assessment items from 17 to 20. Respondents are presented with 20 specific symptoms of PTSD and asked to rate how much they have been bothered by that problem in the last month on a 4-point Likert scale, ranging from 1(not at all) to 4 (extremely) (Weathers, Litz, Keane, Palmieri, Marx, & Schnurr, 2013).

Preliminary validation of the PCL-5 appears to mirror that of the previous version. Current evidence suggests that a 5 point change in response indicates a reliable change while a 10 point change in response represents a clinically significant change. Research is being conducted to further validate the instrument (Weathers, Litz, Keane, Palmieri, Marx, & Schnurr, 2013).

*SF-36v2Quality of Life Assessment*

The SF-36v2 is a multi-purpose, health related quality of life survey with only 36 questions. It yields an 8-scale profile of functional health and well-being scores as well as psychometrically-based physical and mental health summary measures. Reliability estimates for physical and mental summary scores usually exceed 0.90 (Ware, Kosinski, & Keller, 1994). Studies to date have yielded content, concurrent, criterion, construct, and predictive evidence of validity. Forty-four (81%) of the SF-36v2 concepts have been linked to all three components of the ICF (body functions, activity and participation, environment) making it an effective tool for

assessing behavior changes related to quality of life within the ICF framework (Geyh, Cieza, Kollerits, Frimby, & Stucki, 2007).

*World Health Organization Disability Assessment Schedule 2.0 (WHODAS-II)*

The WHODAS-II assessment is a 36- item questionnaire measuring functioning and disability according to the ICF. It is well established as an effective tool for assessing behavioral and functional change in treatment trials. Extensive testing has shown the WHODAS-II to have good test-retest reliability ranging from 0.69-0.89 on the item level and 0.93 to 0.98 on the domain level and excellent total internal consistency ( $\alpha = 0.96$) for 36 items (Ustun et al., 2010). The assessment can be self-administered, conducted by interview, or administered by proxy.

*Major Depression Inventory (MDI)*

The MDI (Bech, 1998) is a 12-item self-report measure of the presence and severity of depressive-type symptoms. The MDI consists of a six-point scale for each item. The items of the MDI correspond to ten symptoms of depression identified in the DSM-IV-R major depression symptoms, with the exception of self-esteem. The MDI has been found to be superior to the Beck Depression Inventory because the BDI's clinical validity is limited in addressing the DSM-IV symptoms of depression (Konstantinidis, Martiny, Bech, & Kasper, 2011).

Test Procedures

All veterans meeting the specified criteria and who have signed the informed consent form will be enrolled in the study. The veterans will be randomly assigned by a blinded member of the research team to an EAA treatment group or wait-list group. The assigned number will be used for all data coding and analyses. Each EAA participant will be evaluated by a physical therapist, occupational therapist, or certified riding instructor to determine the physical goals and objectives of the intervention sessions. The participants will begin each intervention session with

a fellowship time, which consists of a light meal and social time with other veterans. The participant will then be matched with a veteran volunteer and a horse. Because this program addresses mind, body, and spirit, the decision for which horse and which volunteer veteran a participant works with will be made by the staff team. Matching criteria will include: a request for a specific horse by the participant, the weight of the participant and stature of the horse, the physical limitation of the participant, the physical limitations of the horse, and how well the horse and participant partner.

*EAA Protocol*

A standardized, eight week EAA curriculum, *Rainier Therapeutic Riding's Riding Through Recovery*, will be used at all five sites. Baseline assessments will be conducted for all participants in both the EAA group and the wait-list group. The EAA program will consist of eight, 90 minute weekly lessons. The first few lessons will focus on developing a relationship between the horse and the participant without riding. The last two lessons will include riding instruction if the participant chooses to ride. The PCL-5 will be administered pre and post as well as 2 months following the program. The SF-36v2, WHODAS-II and the MDI will be completed before beginning the program, at four weeks (mid-treatment), post-treatment and 2 months follow-up. Semi-structured questions will be answered post-treatment. In addition, the WHODAS-II proxy form will be completed by the participant's spouse, caregiver or physician pre and post intervention. The wait-list group will participate in treatment as usual (TAU) and will be assessed using the same instruments and time sequence with the exception of the post-treatment semi-structured questions and the 2 month follow-up. After the first eight weeks, the wait-list group will participate in the EAA intervention. (See Table 4 in attachments for complete timeline of treatment and data collection).

**Analysis**

The design of the study allows for multiple forms of data analysis to test the project's hypotheses. A comparison of the treatment group's values to the control group values on the variables of interest during and at the end of the first 8 weeks in a cycle will give the most direct evidence of whether the treatment is causing any effects. This can be done using a latent growth curve (LGC) model, which is a general form of analyzing longitudinal data (Bollen & Curran, 2006). Llabre, Spitzer, Siegel, Saab, and Schneiderman (2004) argue that LGC models have advantages over model traditional model such as repeated-measures ANOVA (RM-ANOVA), such as (a) being able to account for measurement error, (b) a variety of options in specifying the outcome variance/covariance and time between measurement occasions, and (c) the ability to handle missing data using modern methods (e.g., full information maximum likelihood; Enders, 2011). Moreover, if the measurement error is minimal, the outcome variance/covariance has compound symmetry, and there is no missing data, then the LGC specification is identical to a RM-ANOVA (Voelkle, 2007). In addition, as all groups will receive treatment at some point during the study, the data can be viewed as an interrupted time series (Shadish, Cook & Campbell, 2002) with different entry dates into treatment. This too can be incorporated into the LGC model (Duncan & Duncan, 2004).

**V. PROPOSED TIMELINE (See Proposed timeline chart with milestones in attachments).**

**VI. INTENT TO PUBLISH**

Dissemination of results

The data collected from this study should result in several manuscripts. The manuscripts will be submitted for publication in several journals. Possible journals include the Journal of Rehabilitation and Research Development, Journal of Traumatic Stress, Military Medicine, and

the Animal-Human Interaction Bulletin. Proposals for presentations at conferences will be submitted to national and international professional organizations including the Professional Association for Therapeutic Horsemanship International Conference, the American Public Health Association national conference, American Academy of Health Behavior and the International Association of Human-Animal Interaction Organizations.

All budget items must be related directly to the research question and methodology and will be prorated. Larger grants may be paid in progressive payments, checks written only after progress reports are sufficiently completed. All budget referrals should be related in U.S. dollars. **Please provide itemized budget <u>and</u> narrative justification. No indirect costs are allowed.** There are no word limits to this section, however, please be concise in explanation.

**TOTAL GRANT REQUEST (US Funds): $ 50,000.00**

1) **PERSONNEL:** *(Principal investigator, co-investigator, statistician, research assistant)* Please describe scope of work, salary, fringe benefits, FTE

   **Personnel Total: $ 18,444.00**

   **Personnel % of total budget: 37%**

2) **PERMANENT MINOR EQUIPMENT:** Itemize and describe purpose, justification of needs, how it will be acquired, etc.

   **Permanent Equipment Total: $ $196**

   **Permanent Equipment % of total budget: .4%**

3) **CONSUMABLE SUPPLIES:** Itemize and describe justification of needs, how it will be acquired, etc.

   **Consumable Supplies Total: $250**

   **Consumable Supplies % of total budget: .5%**

4) **CONSULTANT COSTS**: Describe rate of pay, scope of work, justification of need, etc.

   **Consultant Costs Total: $ 16,000.00**

   **Consultant Costs % of total budget: 32%**

5) **TRAVEL**: *(Will only cover subject travel reimbursement or for meeting of work groups.*)

   **Travel Costs Total: $ 3,110.00**

   **Travel % of total Budget: 6.1%**

6) **CLIENT-RELATED EXPENSES**: Itemize and describe all related costs.

**Client-Related Expenses Total: $ 12,000.00**

**Client-Related Expenses % of total budget: 24%**

*7)* **HORSE EXPENSE:** *(Must be directly related to research question and methodology.)* Explain cost basis related to percentage of time used in project.

**Horse Expense Total: $ 0**

**Horse Expenses % of total budget: 0**

8) **BUDGET JUSTIFICATION:** Please provide any further budget justification or explanation here.

**A. PERSONNEL**

Funds are requested for support of Key Personnel. Total salary (with fringe benefits) requested is **$18, 444.00** ($6,328 for two graduate students). We are also requesting an additional **$16,000** in administration fees for site supervisors. (Total= **$34, 444.00)**

**Beth Lanning, PhD**, Project Director/Principal Investigator, (Effort: partial summer for Year 1) will be responsible for overall study implementation and coordination and day-to-day direction of this project. Dr. Lanning has conducted several studies investigating the effects of therapeutic riding on vulnerable populations such as soldiers in transition (from active duty to civilian life) and children with Autism Spectrum Disorders (ASDs). She was also the lead author on the pilot study described in the research narrative section of the proposal.

**Dr. Alex Beaujean, PhD** (Statistical consultant) will oversee data analyses for the study. Dr. Beaujean is the Director of the Baylor Psychometric Laboratory and has strong expertise in statistics and psychological measurements.

**To be determined**. Graduate research assistant in statistics and in public health. The statistic research assistant will be supervised by Dr. Beaujean and will assist will all data analysis and

report preparations. The public health research assistant will be supervised by Dr. Beth Lanning and will assist with data entry, assessments and other grant related administrative duties.

**Other Significant Contributors:**

**Nancy O'Meara Krenek, PT, PATH Certified Therapeutic Riding Instructor,** Consultant/site supervisor for two site locations, is the founder and director of the Ride On Center for Kids (ROCK) and is the lead physical therapist for the center. She has 13 years of experience with therapeutic riding and individuals with disabilities. Mrs. Krenek will serve as a consultant on all interventions and activities conducted at ROCK and Courtney Cares (Texas A&M Systems) and assist in the recruitment of the participants. She will also participate as the lead TR instructor for the intervention. Mrs. Krenek will be the site supervisor for two locations and a consultant for the other sites ($2,000.00 per location plus $100.00 per participant).

**Karen Fraser, PATH Certified Therapeutic Riding Instructor/Director of Veterans program.** She will act as the consultant/site supervisor for R.E.A.C.H therapeutic riding center. Ms. Fraser will serve as a consultant on all interventions and activities conducted at REACH and assist in the recruitment of the participants. She will also participate as the lead TR instructor for the intervention. Ms. Fraser will be the site supervisor for REACH (2,000.00 plus $100.00 per participant).

**Elisia Fernandez Mutter, PATH Certified Therapeutic Riding Instructor, Equine Specialist in Mental Health and Learning.** Ms. Mutter will be the consultant/site supervisor for the Rainier Therapeutic Riding Center. She will serve as the consultant on all interventions at the Rainer site and assist in the recruitment of the participants. She will also train all site instructors on the use of the standardized curriculum used in the study ($2,000.00 plus $100.00 per participant).

**Laura Berlin, PATH Certified Therapeutic Riding Instructor.** Ms. Berlin will be the site supervisor for Triple H Equitherapy. She will serve as the consultant on all interventions at the Triple H. ($2,000.00 plus $100.00 per participant).

**B. TRAINING**.

The primary site consultant and the PI will travel to Rainier Therapeutic Riding Center in Yelm, Washington to attend periodic training for implementation of the standardized curriculum, *Rainier Therapeutic Riding's Riding Through Recovery* which will be used in the study. (Airfare, Meals, lodging for two persons, **$1,800.00**)

**C. ADDITIONAL TRAVEL.**

The PI will need to make several trips to the testing facilities. Two of the testing facilities are 90 miles from Baylor University. In addition, the PI will need to meet with the staff at Rainer at the conclusion of the study to conduct follow-up training and assessments. (Car travel= .58/mile, Airfare to Yelm, Washington and lodging, **$1,310.00**).

**D. PARTICIPANT INCENTIVES**

In order, to improve adherence to the study protocol, the participant will receive a monetary incentive. Additional monetary incentives will be given to the caregiver or psychiatrist for completing the pre and post assessment forms for the participants. Each participant will receive $100.00 for completing the assessments (baseline, 4 weeks and post-intervention). In addition, they will receive $50.00 to complete the 2 month follow-up assessment. The caregiver or psychiatrist completing the pre and post assessments will receive $50.00/participant. Total cost

breakdown includes: 60 participants x $100/participant + 60 participants x $50/participant follow-up + 60 participants x $50/participant for caregiver assessment= **$12,000.00**.

**E. MINOR EQUIPMENT**

All but one of the instruments used in this study are public domain and therefore can be obtained at no cost. The SF36v2 Quality of Life assessment requires a user license and processing fee for data analysis, which has been purchased. Additional assessment will need to be purchased. Digital recorders will be needed to record answers to the semi-structured post intervention questions. Additional supplies are needed for assessment packages and shipping. **$ 446.00.**

**OTHER INCOME SOURCES and ANTICIPATED FUNDING SUPPORT:**

**a. Active/Committed:** Is this project being funded by other sources (federal, institutional and/or private grants or other sources)? Please provide source/institution name, project titles, specified designations and restrictions, starting and ending dates and amounts. Do not include general or overall program support.

**University Research Committee Grant, Baylor University. December 15, 2013-May 31, 2014.**

**Project Title**: Examination of the effects of equine assisted activities on PTSD symptoms, quality of life and participation in combat veterans using the international classification of functioning, disability and health (ICF) as a conceptual model: Initial phase

**Total Active/Committed: $6,750.00**

**b. Pending:** Is support for this project being sought elsewhere? Please provide source/institution name, project titles, specified designations and restrictions, starting and ending dates and amounts.

**ISAZ/WALTHAM® Collaborative Research Award. August 1, 2015 – May 31, 2015.**

**Project title:** Examination of the effects of equine assisted activities on PTSD symptoms, quality of life, functioning and participation in combat veterans.

**Total Pending: $ 45,000.00**

**c. Related Support:** List all other sources of support, pending or current, including federal (NIH, VA, NSF, etc.), foundation, industrial, or other. Give complete titles of all grants as well as total funding, yearly funding, funding for your salary, funding for your research, and inclusive funding dates.

**Total Related Support: $ 0**

## VIII. LAY-LANGUAGE ABSTRACT

**Background.** Many veterans are returning home from the wars in Iraq and Afghanistan with posttraumatic stress disorder symptoms. These mental wounds are affecting the quality of life of both the veterans and their family members, leaving veterans feeling helpless, isolated and suicidal. While treatment programs are available to help veterans transition back into civilian life, many are reluctant to seek help in VA settings and are looking for alternative therapies outside of the military. Programs which include animals, especially horses, as partners are gaining in popularity and appear to help reduce some of the symptoms associated with trauma. Many of these programs, however, have not been studied. Our pilot study is the first known published study to examine the effects of human-horse interactions and therapeutic riding on quality of life and depression symptoms of combat veterans.

**Plan.** Our current study will expand on the information obtained from the pilot study by investigating the effects of an eight-week equine assisted activities (EAA) intervention on PTSD symptoms, quality of life and impaired functioning. We will also use the international classification of functioning, disability and health (ICF) as a model to help guide the study. This unique perspective will help us better understand not only how EAA affects behavior, but also why EAA appears to positively influence quality of life and encourages veterans to participate in life activities. Seventy-five combat-veterans, meeting all study criteria, will be recruited to participate in the study and randomly assigned to an eight week EAA intervention or a waitlist. Following the first eight weeks, the waitlist group will participate in an identical EAA intervention. We will assess behavior changes at the beginning, 4 weeks, at the end, and two-months follow up. Data analysis comparing the behavioral changes of the EAA group to the

waitlist group will be conducted. Further, the relationships of the various behaviors (e.g., functioning, participation, emotional control) will be examined to determine how and why EAA affects quality of life.

**Team.** Our research team has extensive experience working with veterans in therapeutic riding programs. Several members of the team where involved in the first horses and veterans program in the United States. This strong team will be led by a professor of community/public health who has a successful track record of conducting research, administrating grants, and publishing results: including the pilot study. We plan to present and publish results from the proposed study.

## IX. BIOGRAPHICAL SKETCH OF PRINCIPAL INVESTIGATOR

**BIOGRAPHICAL SKETCH**

Provide the following information for the Senior/key personnel and other significant contributors. Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

| NAME<br>Lanning, Beth A. | POSITION TITLE<br>Associate Professor, Health Education<br>Baylor University |
|---|---|
| eRA COMMONS USER NAME (credential, e.g., agency login)<br>Beth_Lanning | |

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

| INSTITUTION AND LOCATION | DEGREE *(if applicable)* | MM/YY | FIELD OF STUDY |
|---|---|---|---|
| Baylor University, Waco, Texas | B.S.Ed. | 1989 | Corporate Fitness |
| Baylor University, Waco, Texas | M.S. Ed. | 1991 | Exercise Phys./Health |
| Texas A&M University, College Station, Texas | Ph.D. | 1997 | Health Education |

### A. Personal Statement

The purpose of the proposed study is to examine the effects of therapeutic riding as an intervention for veterans with PTSD symptoms and/or functional impairment. I believe I have the expertise, leadership ability and motivation to successfully carryout the proposed research plan. I have a broad background in health and health promotion, specifically in assessing and improving quality of life in various populations. For the past six years, I have been conducting research on how the animal-human bond can improve quality of life. These studies have examined the effects of equine-assisted activities as an intervention with at-risk youth, soldiers, and children with ASDs. Two of these projects (equine assisted activities-soldiers in transition, and children with ASDs) included several current team members. In addition to my research experience related to the proposed project, I have experience leading and participating in both externally and internally funded projects.

### B. Positions and Honors

**Positions and Employment**

Sept. 1991-May 1994 McLennan Community College. Waco, TX. Wellness Coordinator/Instructor.

| | |
|---|---|
| April 1995 & Feb. 1994. | McLennan Community College, Continuing Education Instructor. |
| May 1995- 1998 | Youth Connection, Inc., Waco, TX. Program Coordinator. |
| Sept. 1992- Aug. 2000 | Baylor University, Waco, TX. Health Education Lecturer |
| August 2000-2006 | Baylor University, Waco, TX. Assistant Professor. Health Education |
| August 2006-present | Baylor University, Waco, TX. Associate Professor, Director of the Undergraduate Community Health Program. |

**Other Experience and Professional Memberships**

| | |
|---|---|
| 1998-2010 | C.H.E.S. (Certified Health Education Specialist). |
| 2000-present | SOPHE (Society of Public Health Education) |
| 2006-present | PATHInt.2006-present |
| 2010-present | M.C.H.E.S. (Master Certified Health Education Specialist) |
| 2011-present | American Academy of Health Behavior, accepted member. |

**Recent honors**

2001 Non-Tenured Tenured Track Outstanding Teaching Award- School of Education representative.
2003 Research Sabbatical, Summer
2004 Non-Tenured Tenure-Track Outstanding Scholarship Award- School of Education Representative.
2005 Research Sabbatical, Summer
2006 Tenured Faculty Member

**C. Selected Publications, Presentations, and Manuscripts**

1. Bowden, R. G., Lanning, B. A., Doyle, E. I., Slonaker, B., Johnston, H M., Scanes, G. (2008). The effects of weight loss attempts, exercise initiation, and dietary practices on health related quality of life. *Applied Research Quality Life*, 3: 149-160.
2. Lanning, B. A. & Doyle, E.I. (2010). Health literacy: Developing a practical framework for effective health communication. *Journal of American Medical Writers Association*; 25(4):155-161.
3. Lanning, B. A., & Krenek, N. (2013). Examining effects of equine-assisted activities to help combat veterans improve quality of life. *Journal of Rehabilitation Research and Development.* 50(8):xv–xxii. http://dx.doi.org/10.1682/JRRD.2013.07.0159
4. Frederick, K.E., Ivey-Hatz, J., Lanning, B. A. Not just horsing around: The impact of equine-assisted learning on levels of hope and depression in at-risk adolescents. *Journal of Adolescence*. Submitted April 2013.
5. Lanning, B.A., Baier, M., Ivey-Hatz, J., Krenek, N. & Tubbs, J. D. (2014). Effects of equine assisted activities on autistic disorder. *Journal of Autism and Developmental Disorders*. Accepted. February, 2014.

**Selected Peer-reviewed Conference Presentations related to proposed study**

1. Lanning, B.A., Garner, B., Alford, K. Equine Therapy and Quality of Life: Finding the Evidence. *2007 North American Riding for the Handicapped Association National Meeting,* Anaheim, CA. November 14-17, 2007.
2. Lanning, B. A., O'Meara Krenek, N., Schroeder, J., Reese, S. Changes in quality of life indicators using the NARHA Horses for Heroes program: A preliminary report. *2008 NARHA National Meeting,* Hartford, Connecticut. October 29-November 1, 2008.
3. Lanning, B. A., *NARHA Horses for Heroes Research.* NARHA National Conference and Annual Meeting. Fort Worth, Texas. November 18-21, 2009.
4. Lanning, B.A., Krenek, N., Ivey-Hatz, J., Muir-Broudeau, J. *The Efficacy of EAA/EATas a Treatment Modality for Children with ASD.* Presentation. Professional Association of Therapeutic Horsemanship International Annual Meeting, Bellevue, WA., October 2012.
5. Lanning, B.A.. Krenek, N., Sjule, S. *Post traumatic growth versus PTSD treatment: The role of equine assisted activities in the growth process*. Presentation. Professional Association of Therapeutic Horsemanship International Annual Meeting, Bellevue, WA., October 2012.
6. Frederick, K., Lanning, B.A., Hatz, J. *The Impact of Equine- Assisted Learning on Levels of Hope and Depression in At-Risk Adolescents*. Poster Presentation. Society for Public Health Education National Meeting, Baltimore, MD., March 2014.

**D. Research Support: Completed**

University Research Council Grant Lanning (PI) December 2013-May 2014
Baylor University
Examination of the effects of equine assisted activities on PTSD symptoms, quality of life and participation in combat veterans using the international classification of functioning, disability and health (ICF) as a conceptual model. Initial Phase.

Faculty Research Investment Program Grant Lanning (PI) June 2010-May 2011
Baylor University
Assessing Quality of Life Changes in Children with Autism who participate in an Equine-Assisted Therapy Program. The goal was to assess behavioral changes related to quality of life of children with ASDS who participated in a therapeutic riding intervention.
Role: PI

University Research Council Grant Ivey-Hatz (PI) June 2010-May 2011

The Effect of Extreme Camps on Self-Efficacy, Self-Perceptions, and Behaviors of Youth with Autism Spectrum Disorders.
Role: Co-PI

Attorney General's Office, Irons (PI) July 2008-Aug. 2009
Advocacy Center for Crime Victims and Children in Waco
Sexual assault risk factor identification and community needs assessment. The goal of this research was to focus on primary prevention by examining community risk factors that contribute to sexual violence and develop programs needed to address those factors.
Role: Co-PI

Texas Resources For Iraq-Afghanistan Krenek (PI) 2007- 2009
Deployment Fund (TRIAD San Antonio Foundation.
Assessing changes in quality of life indicators of soldiers participating in a equine-assisted intervention.
The goal of the study was to assess quality of changes of the soldiers participating in the NARHA Horses for Heroes program.
Role: Co-PI.

Institute of Faith Health Research of Dallas. Doyle (PI) 2005- 2006
Community based participatory research: a health promotion pilot in Roseland Homes, East Dallas.
Helped to develop the health promotion program utilized in the study.
Role: Co-PI

Curves International. Kreider (PI) 2004-2006
Effects of the Curves for Women® Fitness and Weight Loss Program on Body Composition, Metabolism, and Exercise Capacity in Sedentary Overweight Females.
My role was to analyze the body image changes and self-esteem and quality of life of the women participating in the Curves program.
Role: Co-Investigator

## HUMAN SUBJECTS
COMPLIANCE WITH U.S. GOVERNMENT REQUIREMENTS

The following statements are signed by an individual authorized to act for the institution and to assume on behalf of the institution the obligations imposed by the following:

The Baylor University (Principal Investigator or Institution) agrees that if a research grant is awarded by the Horses and Humans Research Foundation (HHRF) to Beth Lanning, PhD (Applicant/Principal Investigator) for the project *Examination of the effects of equine assisted activities on PTSD symptoms, quality of life, and participation in combat veterans.* (Project Title) and if human subjects are used in any of the activities supported by such award, that it will comply with all applicable U.S. Department of Health and Human Services regulations with respect to the rights and welfare of such subjects. To the extent allowable by the State of Texas, the Baylor University (Institution) agrees to indemnify and hold HHRF harmless from any claims arising from such activities, and acknowledges that HHRF does not and will not assume responsibility for the subjects involved.

**SIGNATURE OF APPROVAL BY THE DEAN OR HEAD OF INSTITUTION ON BEHALF OF INSTITUTION**

Elizabeth Davis
Signature

Elizabeth Davis, Executive Vice President and Provost
Type/Print Name and Title of Dean or Head of Institution

May 12, 2014
Date

## ANIMAL SUBJECTS
COMPLIANCE WITH GOVERNMENT REQUIREMENTS

The following statements are signed by an individual authorized to act for the institution and to assume on behalf of the institution the obligations imposed by the following:

The Baylor University (Principal Investigator or Institution) agrees that if a research grant is awarded by the Horses & Humans Research Foundation (HHF) to Beth Lanning, PhD (Applicant or Principal Investigator) for the project *Examination of the effects of equine assisted activities on PTSD symptoms, quality of life and participation in combat veterans* (Project Title) and if animal subjects are used in any of the activities supported by such award, that it will comply with all applicable U.S. Department of Health and Human Services regulations with respect to the rights and welfare of such subjects. To the extent allowable by the State of Texas, the Baylor University (Institution) agrees to indemnify and hold HHRF harmless from any claims arising from such activities, and acknowledges that HHRF does not and will not assume responsibility for the subjects involved.

**SIGNATURE OF APPROVAL BY THE DEAN OR HEAD OF INSTITUTION ON BEHALF OF INSTITUTION**

Elizabeth Davis
Signature

Elizabeth Davis, Executive Vice President and Provost
Type/Print Name and Title of Dean or Head of Institution

May 12, 2014
Date

## XI. RESEARCH GRANT CONDITIONS OF AWARD

1. At least one member of the research team must be fluent in English and published in peer-reviewed English language journals.
2. No institutional overhead or other indirect costs will be paid and should not be included as part of any grant request. A letter to your institution explaining this condition can be requested if needed. Beware that substantive equipment costs could work against the success of the grant request.
3. All funds awarded shall be used in accordance with the submitted and approved proposal and accompanying budget. Any unused portion thereof shall be returned to the Horses and Humans Research Foundation (HHRF). If an unforeseen problem occurs with the study design, notify HHRF immediately. Potential changes to the study design with additional financial assistance from HHRF may be considered to salvage the study and still lead to a favorable outcome.
4. Grant awards will be made in US dollars. Fifty percent will be awarded after the midpoint report is accepted and the remainder will be awarded when the project is fully completed, unless other arrangements have been specified and agreed to. The value of the grant will not be adjusted for inflation, cost over runs, or foreign exchange rate fluctuations. It is the responsibility of the recipient to manage these potential variables (example: if grant budget deals in euros, a loan could be purchased at the time of award, in US dollars, against the euro).
5. At the midpoint of the grant period a progress report and financial report must be submitted. A final report must be submitted within 60 days of the completion of the project. The final report shall include a scientific abstract, summary data tables, a financial report, and a less-technical lay language article (400 words) to potentially be used in HHRF and related publications as determined by HHRF. Confidential data that could jeopardize formal publication in a peer-reviewed journal should not be disclosed in the lay articles. If a delay in project completion of more than 3 months duration is anticipated, HHRF must be notified promptly with a brief explanation and a request for extension. All investigators are encouraged to communicate and work with HHRF for the best possible outcome of their study. Failure to comply with the above conditions may result in revoking of all award funding.
6. The Principal Investigator must assure HHRF of his or her intended work location. HHRF must be advised at the time of application of all moves, contemplated or real. Changes of address, phone number, fax number and email *within the same institution* must be promptly conveyed to HHRF. Changes in site location during a funded period must be approved by HHRF.
7. All publications (including poster abstracts at medical conferences) resulting from HHRF-funded research must include HHRF in a footnote/credit line/disclosure, and copies of such publications must be provided to HHRF. All publicity and information disseminated about such research must acknowledge HHRF support. This is an essential part of HHRF's conditions of award. Publicity or information about the project is used to keep supporters to HHRF informed about how their donations are being spent. This

condition of award does NOT involve disclosure of any information that might jeopardize the applicant's ability to formally publish their findings.

8. The recipient of any research grant awarded must certify that any research, including work involving human and/or animal subjects, will be conducted according to the rules and regulations of the United States Department of Health and Human Services. The recipient must agree to hold HHRF harmless from any and all claims which may arise from any associations/issues related to such research.
9. All studies involving therapeutic riding horses must comply with accepted industry standards for care, treatment, and humane work load. All mounted work must comply with accepted industry standards for safety – including a certified instructor/therapist or evidence of equivalent standards. Therapeutic riding program sites must be accredited by or provide evidence of equivalent standards for facility safety.
10. A one-year grant period is assumed. HHRF may approve the funding of a multi-year project, with funding of subsequent years pending the successful completion of the initial year. Applicants must consult HHRF prior to submitting a multi-year application.
11. Recipients of HHRF grants will be committed to a serious effort to publish resulting research findings in a peer-reviewed journal. HHRF will be kept informed of publication efforts.
12. All grant applicants must include one signed copy of this "Research Grant Conditions of Award" as a necessary part of their grant application to HHRF.
13. The Foundation reserves the right to terminate an award if the grant holder or staff funded by the grant is in breach of any of the conditions of award or becomes unfit or unable to pursue the work funded by the grant.

*I have read and understood HHRF's "Research Grant Conditions of Award" and my signature below signifies that I agree to abide by all conditions specified.*

Principal Investigator's signature: Beth Lanning Date: 5/12/14