UNIVERSITY of MISSOURI

OFFICE OF RESEARCH

SPONSORED PROGRAMS ADMINISTRATION

October 31, 2012

Horses and Humans Research Foundation 16 Daisy Lane Chagrin Falls, OH 44022 440.543.8306

RE:

Therapeutic Horsemanship for Veterans (ToRCH for Veterans) University of Missouri-Columbia Proposal #0036732/00040568

The University of Missouri takes exception to and will need to negotiate language prior to accepting an award from the Horses and Humans Research Foundation:

1) Both the Human Subjects and Animal Subjects forms need modified to read:

"To the extent allowable by the State of Missouri and without waiving sovereign immunity, the University of Missouri (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."

2) Item 8 of the Research Grant Conditions of Award needs modified to read:

"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 the burney in the permitted by applicable law and without waiving sovereign immunity hold HHRF harmless from any and all claims which may arise from any associations/issues related to such research."

Reason for requested revision: As an entity of the State of Missouri we cannot agree to waive our rights to sovereign immunity.

If an award is made, it should be to *The Curators of the University of Missouri*. Please contact Amy Welch, Senior Grants and Contracts Administrator at 573/882/1290 or email welchamy@missouri.edu for any administrative questions and/or negotiations.

Sincerely,

Karen M. Geren

Authorized Signer, Grants and Contracts Submissions Specialist - Tiger Team

Office of Sponsored Programs Administration

University of Missouri | 310 Jesse Hall |Columbia, MO 65211

Phone: 573.882.4451 | Fax: 573.884.4078 | gerenk@missouri.edu

Horses and Humans Foundation Grant

I. Cover Page

HHRF Research Grant Application Cover Page

Title of Project: Therapeutic Horsemanship for

Veterans (ToRCH for Veterans)

Submission Date: Nov. 1, 2012

Principal Investigator Name and Title: Rebecca A. Johnson, PhD, RN, FAAN, Professor and Director, Research Center for Human Animal Interaction, University of Missouri, College of Veterinary Medicine

Contact Name and Title: Jennifer E. Duncan, Director, Office of Sponsored Programs Administration (NOTE: The contact person is the only person with whom HHRF will have direct contact. The contact person receives all letters and notification from the HHRF office.)

Institute: Research Center for Human Animal Interaction University of Missouri, College of Veterinary Medicine

Address (provide physical AND mailing addresses, if different):

900 East Campus Drive Columbia, MO 65211

Telephone Number: 573-882-2266

FAX Number: 573-884-5044

URL: www.rechai.missouri.edu

Email Address: rajohnson@missouri.edu

Primary focus area of the investigation (i.e. mental health, occupational therapy, education, recreation, the horse-human relationship): Outcomes measured from human medicine, psychology, and occupational therapy.

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:

Therapeutic Horsemanship, Wentzville, MO

- Sandy Rafferty, MA, OTR/L, Program Director at Therapeutic Horsemanship, Wentzville, MO. PATH #96 Level II Therapist
- Melanie Wood, MS, OTR/L PATH # 68445. Level II Therapist
- (TH has several other occupational and physical therapists who may be engaged, most are PATH registered level II therapists (any who treat research participants will be Level II)

Ride-On St. Louis, Kimmswick, MO

- Marita Wassmann, Program Director, PATH Certified Instructor: PATH #37916
- Anne Cochran, PT, Physical Therapist at Ride-on St. Louis, Kimmswick, MO, PATH #55198, Level II therapist. AHA#79.

Cedar Creek Therapeutic Riding Center (CCTRC), Columbia, MO

- Kim Scholl, Physical Therapist PATH Certified Instructor: PATH # 6042500
- Karen Grindler, PATH Certified Instructor # 11735
- Constance Crumpton, Occupational Therapist at CCTRC, NBCOT # AA490128, Missouri License # 001064, PATH Certified Instructor # 80370

Are all listed personnel certified to provide the activities? Yes (If yes, please provide member numbers with each name)

Certifying organization's name, website and contact information, or evidence of equivalent standards adhered to (please attach explanation if necessary):

PATH: www.path.org: All treating therapists are registered Level II with PATH.

AHA: www.americanhippotherapyassociation.org provides education to allow therapists to register with PATH and all have taken level I and II courses from AHA.

Site standards for EAA/T

Is the site providing EAA/T programming accredited to do so? Yes No Member Number: Accrediting organization's name, website address and contact information, or evidence of equivalent standards adhered to (please attach explanation if necessary):

Will others collaborate or consult with you on this project? XX Yes, letters attached

If yes, list Individuals or Organizations collaborating on project

Therapeutic Horsemanship: PATH #1483

Ride-On St. Louis: PATH # 45514

Cedar Creek Therapeutic Riding Center PATH# 11735

Attach letters to you that state collaborating individuals or organizations agreement to do so.

Brief description of project:

The proposed study uses a randomized experimental design with repeated measures and wait-list control group to study 40 US military veterans by testing efficacy of a 6-week human-horse

interaction and systematic therapeutic horseback riding program in: decreasing PTSD symptoms, increasing coping self efficacy, emotion regulation, and social engagement.

Pilot Study Completed? Yes No Completion Date:
Is project Institutional review Board approved? Pending
The MU IRB and VA R&D applications will be submitted upon commitment of funding.
Start Date of Project: April 1, 2013 End Date of Project: March 31, 2014
Amount requested from HHRF: \$ 50,000

II. Scientific Abstract

Large numbers of post-deployed U.S. veterans diagnosed with Post Traumatic Stress

Disorder (PTSD) and/or Traumatic Brain Injury, make effective interventions urgent to reduce symptoms and increase veterans' coping. PTSD includes anxiety, flashbacks, and emotional numbing. Symptoms expand health care costs for stress-related illnesses making veterans' civilian life difficult.

The proposed study uses a randomized experimental design with repeated measures and wait-list control group testing efficacy of a 6-week human-horse interaction and systematic therapeutic horseback riding program in: decreasing PTSD symptoms, increasing coping self efficacy, emotion regulation, and social engagement. Participants will be over age 18, weigh under 250 pounds, able to walk 25 feet independently (or with assistive device), who consent to participate and whose Health Care Provider agrees.

The Riding Group spends one hour weekly interacting with and riding the same horse at one of three PATH-accredited riding centers in Mid-Missouri supervised by an Occupational Therapist, PATH-certified instructor, leader and side walkers as needed. Riding will be directed by a systematic lesson plan. Data collection occurs at baseline, 3 weeks, and 6 weeks. The Control Group will be assessed at the same intervals and again 3 weeks and 6 weeks after joining the Riding Group.

III. Need/Justification

A. Military deployment & PTSD. The U.S. census reports that in 2010 over 23 million surviving U.S. veterans (500K in Missouri) had been in active military service in WWII, Korea, Vietnam, Gulf War and Operations Enduring Freedom, Iraqi Freedom, and New Dawn (Census Bureau, 2010). Post Traumatic Stress Disorder (PTSD), an anxiety disorder, occurring after exposure to a life threatening event or injury during combat, is a major concern for veterans (U.S. Department of Veterans Affairs, National Center for PTSD [US DVA, NCPTSD], 2011a). The *Diagnostic and Statistical Manual of Mental Disorders* (American Psych Association, 2000) states that PTSD results from exposure to a traumatic event comprising three symptom domains: re-experiencing (reoccurring thoughts or dreams), avoidance and numbing (avoidance of thoughts or feelings of the traumatic event); and arousal (anger outbursts). Symptoms must last more than one month and cause clinically significant function impairment to reach a diagnostic level.

Stigma associated with PTSD promotes beliefs that it is only experienced by those who are weak and that it ends military careers (National Council on Disability, 2009). Fears of stigma may prevent veterans from admitting to symptoms, seeking assistance, or following medical advice.

Little is known about the natural history of PTSD, however the Veterans' After-discharge Longitudinal Registry was recently created in an effort to track development, progression, and responsiveness of PTSD to conventionally administered treatments (Rosen et al., 2012). An estimated 14% of service members returning from Afghanistan and Iraq meet criteria for PTSD (Tanielian & Jaycox, 2008). This conservative rate only takes into account those accessing services, estimated to be approximately 30% at most. Prevalence is anticipated to double within five years after deployment compounding the problem (Hoge, Auchterlonie, & Milliken, 2006). Strong association of PTSD with medical co-morbidities heightens the need to address this

disorder as early as possible to lessen demands for VA medical services as veterans age and disorders become chronic (Nazarian, Kimerling, & Frayne, 2012).

PTSD and traumatic brain injury (TBI) are comorbid making the etiology of symptoms difficult to distinguish (Hoge et al., 2008; Lew et al., 2009). TBI is "the result of a severe or moderate force to the head, where physical portions of the brain are damaged and functioning is impaired" (U.S. Department of Veteran Affairs (VA), 2012, p. 2). TBI sequelae include loss of consciousness or amnesia, change in cognitive functioning, and recall difficulty. It is considered an invisible injury of the wars in Afghanistan and Iraq (Tanielian & Jaycox, 2008). Research is limited on TBI prevalence; however, estimates range from 8% to 15% (Hoge et al., 2008; Vasterling et al., 2006).

PTSD has been associated with physical co-morbidity, poor quality of life, and increased use of health care services (Koren, Norman, Cohen, Berman, & Klein, 2005). Emotional withdrawal and numbing is common among men, but by higher arousal, lack of control, and self persecution occurs among women (Taft, Schumm, Panuzio, & Proctor, 2008). Greater combat exposure has been associated with more PTSD symptoms and poorer readjustment (Taft et al., 2008). Despite knowledge of prevalence and potential for PTSD to negatively impact veterans' reintegration into their families, work, and education, there is a lack of research testing innovative interventions.

The Joint VA/DOD Evidence-Based Practice Workgroup (VA & DOD, 2004) recommends cognitive behavioral therapy (CBT) for treatment of PTSD. CBT is believed to elicit change in the level of PTSD by using some combination of cognitive and behavioral techniques (Foa & Meadows, 1997). Cognitive techniques generally target extinction of conditioned emotional responses by challenging distorted beliefs that result in maladaptive appraisals contributing to maintenance of PTSD (Ehlers & Clark, 2000). These negative emotions can be generated by an individual's cognitive appraisal of the traumatic event (Weiner, 1986) and frequently accompany

PTSD (Jakupcak et al. 2007). Individuals that limit catastrophic appraisals respond better to treatment for PTSD (Ehlers, Mayou, & Bryant, 1998).

Behavioral techniques are used to habituate or extinguish stimuli associated with memories of traumatic experiences (Foa et al., 2009) by presenting a feared stimulus until the fear, anxiety and related problems are reduced. PTSD treatment of combat veterans is usually accomplished with some combination of imaginal exposure and in vivo exposure (Bryant et al., 2008).

Equine assisted experiential therapy has been used with psychiatric patients with horses as

metaphors to facilitate emergence of patients' issues. Structured interaction with horses has also been used. This has been associated with significant decreases in global symptom severity (sustained over 6-months) and significant increases in self-actualization among adult residential psychiatric patients (Klontz, Bivens, Leineart & Klontz, 2007). Horses have also been used in the treatment of PTSD; however, there are no randomized controlled trials supporting the effectiveness of horses in reducing levels of PTSD (Cantin & Marshall-Lucette, 2011). B. Coping with PTSD/TBI: Alcohol intake, Social Support & Physical Activity. Research suggests that a common coping response to PTSD among veterans is alcohol use including newonset binge drinking as well as heavy weekly drinking (Jacobson et al., 2008). High rates of excess alcohol use among veterans with PTSD and increases in use over one year postdeployment have been reported in three studies (Gewirtz et al., 2010; Hoge et al., 2006; Milliken, Auchterloine, & Hoge, 2007). Veterans' attempts to cope with PTSD symptoms through alcohol use may further magnify the challenges of reintegrating into post-deployment life. Positive stress reduction and coping strategies are needed if PTSD symptoms are to be managed effectively.

Two meta-analyses showed that strong perceived social support is associated with fewer PTSD symptoms (Brewin, Andrews, & Valentine, 2000; Ozer, Best, Lipsey, & Weiss, 2003). In general, social support has been found to reduce negative effects of life events, and to positively

affect the perception and interpretation of events (Cohen & Wills, 1985; House et al., 1994; McLeod & Kessler, 1990). Those with limited social support reported more physically and mentally unhealthy days, more depressive symptoms, anxious days, and less vitality (Keyes, Michalec, Kobau, Zahran, & Simoes, 2005).

Preliminary evidence suggests that PTSD and other anxiety/depression related mental health symptoms may also be decreased with physical activity (PA) (Assis et al., 2008; Newman, & Motta, 2007). Physical activity occurring during therapeutic horseback riding (THR) may be a potential positive coping strategy for veterans with PTSD/TBI. In THR, the rider experiences the horse's stride, using core strength to remain erect, making horseback riding not merely a passive experience, but PA. THR in a class setting may foster social support and enhance the veterans' willingness to do other PA. There is reason to expect that veterans may benefit from PA.

C. Human-Horse Interaction, THR, and Stress Reduction. Horses have been widely accepted as companion animals, providing unconditional acceptance. The therapeutic value of the human-equine bond can be categorized into four themes: nurturing, identity, partnership and utility. The interaction between horse and person has been found to elicit feelings of self-efficacy, receptiveness, communication, patience, emotional comfort, safety and trust (Yorke, 2003). Degree of closeness, and ability to touch the horse through ground interaction and THR have been found to facilitate bonding with the horse (Ibid 2003). Experiencing the horse through visual, auditory, tactile, and olfactory senses during quiet interaction is expected to stimulate the relaxation response commonly found in human-small animal interaction research.

Physiologic arousal has been found to decrease in response to human-companion animal interaction. It is now widely accepted that blood pressure drops when people interact with companion animals. Odendaal (2000) found that cortisol levels decreased significantly when people quietly interacted with a dog. Elevated cortisol levels and associated elevated heart rates

have been identified as one component of allostatic load, in which the body develops cumulative effects of repeated adaptations to stress. Long-term stress, activating the "fight or flight" response such as in hyperarousal occurring in veterans with PTSD, has been linked to common chronic illnesses, including hypertension, diabetes and coronary heart disease. Failure of veterans to cope with their PTSD and TBI symptoms may accelerate occurrence of these illnesses. Interacting with a horse may be one way to reduce stress and facilitate coping. D. Therapeutic Horseback Riding. THR is defined as a horse riding program for people with disabilities in which the primary goal is rehabilitation (Meregillano, 2004; Silkwood-Sherer, 2003). THR should not be confused with hippotherapy where physical, occupational, and speech therapists use horses to specifically improve client functioning (Silkwood-Sherer, 2003). It has been evaluated extensively in children (Bertoti, 1988; Biery & Kauffman, 1989; Cawley, Cawley, & Retter, 1993; MacKinnon et al., 1995; Snir, Olin, Avalon, Yazdi, & Inbar, 1988) but less frequently in adults. THR has been implemented in adults and older adults having a variety of problems including general physical impairments (Araujo, Silva, Costa, Pereira, & Safons, 2011; Farias-Tomaszewski, Jenkins, & Keller, 2001; Land, Errington-Povalac, & Paul, 2001) as well as defined physical and psychological disorders such as multiple sclerosis (Hammer et al., 2005; MacKay-Lyons, Conway, & Roberts, 1988; Webster et al., 1995), spinal cord injury (Lechner et al., 2003), spinal stenosis (Ungermann & Gras, 2011), mental retardation (Biery & Kauffman, 1989), and traumatic brain injury (Keren, Reznik, & Groswasser, 2001). Positive physical, psychological, and social outcomes of THR have been documented with adults. Physical benefits include improved sitting posture (Land et al., 2001), motor function (Keren et al., 2001), postural balance (Araujo et al., 2011; Hammer et al., 2005), muscle tension (Hammer et al., 2005; Lechner et al., 2003), balance and gait (Ungermann & Gras, 2011), and pain (Hakanson, Moller, Lindstrom, & Mattsson, 2009; Hammer et al., 2005). Psychological improvements include increased self-efficacy, motivation, and courage (Farias-Tomaszewski et

al., 2001; Fox, Lawlor, & Luttges, 1984; Henriksen, 1971; Rosenthal, 1975), reduced psychological distress (Klontz, Bivens, Leinart, & Klontz, 2007), and enhanced psychological well-being (Klontz et al., 2007; Lechner et al., 2003). Self-efficacy improvement may be an important factor to facilitate veterans' coping with PTSD symptoms. Social benefits include improved social involvement (Hammer et al., 2005). Based on its potential for increasing PA, reducing stress, enhancing coping self-efficacy, and providing social support, THR may be a beneficial activity to reduce PTSD symptoms in veterans.

E. Conceptual Model: Self-Efficacy, Stress Reduction & THR. Social cognitive theory (SCT) provides the theoretical foundation for the study (Bandura, 1986). The theory explains psychosocial determinants of behavior in terms of triadic reciprocal causation (person, behavior/outcome, environment). In this transactional view of self and society, personal factors such as cognitive, affective, and biological events; behavioral patterns; and environmental events operate as interacting determinants that influence each other. For this study, the person will be the veteran and the behavior will be coping with unforeseen events.

According to Bandura, in social cognitive theory, a major factor determining motivation, affect, and behavior is self-efficacy. Persons have a level of confidence, known as perceived self-efficacy, that influences behavior (Bandura, 1986). The actual performance of a behavior (in this case coping) in a specific situation is highly related to the perception that an individual has the ability to perform the behavior. The stronger self-efficacy is perceived, the more active and persistent are the individual's efforts toward the behavior.

Bandura (1986) notes that depression and social support are two key pathways that impact self-efficacy. Depression negatively influences the individual's ability to control life stressors. Aspirations are not achieved and depression is potentiated. Additionally, an inability to develop and maintain social situations and support contributes to depression and lowers self-efficacy. In

the proposed study, perceived coping self-efficacy will be the veteran's perceived ability to successfully respond to unforeseen events.

IV. Research Narrative

- A. Research Questions. The study aims to address the following questions:
 - 1. To what extent is participation in a 6-week THR program associated with improved coping self-efficacy, emotion regulation (mood), and social engagement among veterans?
 - 2. What are the veterans' perceptions of a 6-week THR program?
- **B.** Hypotheses. We will test the following hypotheses:
 - Veterans randomized to participate in the 6-week THR program will have improved self-efficacy, emotion regulation (mood), and social engagement than veterans randomized to a wait-list control group.
 - The number of sessions attended in the 6-week THR program will be positively
 associated with improvements in self-efficacy, emotion regulation (mood), and social
 engagement.
- **C. Design.** The research questions and hypotheses will be addressed through a two-group, randomized trial design with a Riding Group and wait-list Control Group (RG and CG). The CG will enter the treatment condition after the RG has completed it.
- D. Sample. A power analysis was conducted using one primary outcome variable, Coping Self Efficacy (CSES). A sample size of 36 per group (total 18) would provide about 80% power to detect a large effect size of 0.8 (Cohen, 1992), in changes of the overall CSES between two groups (RG vs. CG) using a two sample t-test with a level of significance of 0.05. Considering a 10% attrition rate, 20 veterans per group (total 40) will be recruited. Because we have two study sites in St. Louis and one in Columbia, we will recruit a greater number of participants in St. Louis (14 participants in each group from the St. Louis area and 6 participants in each group

RA Johnson

from the Columbia area, N=40, RG n=20, CG n=20). Veterans, age 18 years or over, out of active military service (not serving in reserve units), diagnosed with PTSD/TBI or both according to ICD-9 diagnostic codes, weight less than 250 pounds, able to walk at least 25 feet without the assistance of a person (but potentially with assistive devices), and are willing to interact with and ride a horse, will be invited to participate in the study.

The criterion of willingness admittedly creates a selection bias. However, it is unethical to force participants to ride a horse if they are unwilling. Thus it would not be possible to conduct the study unless participants are willing. The PI expects that randomization will help to mitigate selection bias given that all participants entering the study do so knowing that they might be assigned to the RG.

e. Participant Identification, Recruitment & Screening. Primary recruitment will occur on a rolling basis through referrals from VA clinicians. We will also send letters to veterans identified through electronic medical records as having a diagnosis of PTSD, TBI or both and who live within a 50 mile radius of study sites. Letters will invite participation and provide a toll-free phone number for interested veterans to call. A reminder post-card will be sent to veterans who have not responded within 2 weeks of the letter. This system is identical to the one currently being used successfully in one of our other veterans studies.

Those who do not reply will receive no further contact. We will also recruit participants by promoting the study at meetings and events and through the listserves and newsletters of veterans' auxiliary, service and social organizations in two study site areas (Columbia, and St. Louis, MO). In these areas, there are well over 50 such organizations. The PI has accessed these networks for recruitment in a preliminary study. We have identified that there are approximately 7,178 (STL 3,748 and COU 3,430) veterans meeting the study selection criteria within a 50-mile radius of the three study sites.

- **F. Randomization.** Randomization will be used to help minimize systematic error. Participants will be randomly assigned to either the Riding Group (RG), or Control Group (CG) conditions. Randomization will occur by computer selection of participants' assigned numbers.
- G. Participant Retention & Attrition. To facilitate retention and minimize attrition we will create a strong study identity using study logos, nametags, and t-shirts given to participants. We will encourage adherence to the intervention by giving participants a small lapel pin with the study logo on it at the mid-point (3 weeks) and end (6 weeks) of the intervention. We will use interactive methods in the riding program to enhance the participants' sense of belonging and will encourage them to make entries in the Riding Diary in which they record their riding class experiences and feelings about them.

We will send email reminders to the CG about their next data collection. At baseline, all participants will be asked to provide the name of someone who can always reach them should their contact information change. The PI is conducting a randomized clinical trial with veterans training shelter dogs, successfully using many of the same recruitment and retention procedures. Thus there is every reason to expect that they will be similarly effective here.

H. Methods (include Pilot Testing and IRB process). Upon funding notification, the project will be submitted to the University of Missouri Health Sciences Institutional Review Board and the University of Missouri Animal Care and Use Committee. Please see Appendix for study safety precautions.

We will pilot test the data collection procedures and THR lesson plan with 2 participants at each study site (n=6). If no changes are needed in the procedures or lesson plan following the pilot, these participants will be included in the main study. If changes are needed they will be made and the main study will begin.

I. Measures. Instruments will take approximately 30 minutes to complete.

RA Johnson s age gender

Demographic Questionnaire (DQ). The investigator-developed DQ address age, gender, race, marital status, years of education and horseback-riding history. It yields categorical data except for the variable, "age in years." The PI has used this instrument successfully in previous studies. Data yielded will enable participant description.

Health History (HH). The HH is an investigator-developed list of common health problems, asking which have been diagnosed by a health care provider, and are under treatment. It also asks about interventions that may be associated with changes in self-efficacy such as yoga (Streeter, Gerbarg, Saper, Ciraulao, & Brown, 2012), massage, meditation, mindfulness (Owens, Walter, Chard, & Davis, 2012), guided imagery, biofeedback, progressive muscle relaxation, acupuncture, and prayer. The instrument asks about drug, alcohol and caffeine intake and tobacco usage. It asks participants to rate their pain during the current week on a 0-10 scale with 0 meaning no pain and 10 meaning the worst pain ever experienced.

Coping Self Efficacy Scale (CSES). The CSES is a 26-item, 11-point analogue scale assessing individuals' perceived ability to cope with life's challenges or threats by using problem-focused coping, stopping of unpleasant emotions and thoughts, and getting support from family and friends (Bandura, 1997; Lazarus & Folkman, 1984). It is also used to assess efficacy of interventions. Participants rate how they believe they could perform behaviors important to adaptive coping. Anchor points are 0 ('cannot do at all'), 5 ('moderately certain can do') and 10 ('certain can do'). The instrument had strong internal consistency (0.80-0.91) and test-retest reliability (0.40 to 0.80) over a three-month period in two studies of men who were HIV positive (Chesney, Neilands, Chambers, Taylor & Folkman, 2006). CSE is a primary outcome measure for the study.

PTSD Checklist--Military Version (PCL-M). The PCL-M is a self-report measure of the 17 DSM-IV symptoms of PTSD asking about problems in response to "stressful military experiences." Respondents rate how much they were "bothered by that problem in the past

month." Items are rated on a 5-point scale ranging from 1 ('not at all') to 5 ('extremely'). A total summed score (range 17 - 85) is obtained. A cut score of 50 is diagnostic of PTSD. The PCL-M has been found to have strong internal consistency (0.94 -0.97), test-retest reliability (0.97 over 3 days), concurrent validity (0.77 -0.93), and diagnostic efficiency with a sensitivity of 0.82 and specificity of 0.84 (Weathers et al., 1999). A 5-point improvement is the minimum threshold for determining positive responses to a treatment and a 10-point improvement identifies a clinically meaningful response (U.S. DVA, NCPTSD, 2011b). PTSD is a primary outcome.

Difficulties in Emotion Regulation Scale (DERS). The DERS contains 36 items measuring "modulation of emotional arousal, but also the awareness, understanding, and acceptance of emotions, and the ability to act in desired ways regardless of emotional state" and is scored on a 5-point Likert-type scale ranging from 1 ('almost never') to 5 ('almost always') (Gratz & Roemer, 2004). It had a strong internal consistency (0.93) and tested well against the Negative Mood Regulation Scale (-0.69) (Ibid). Emotion Regulation is a secondary outcome.

Social and Emotional Loneliness Scale for Adults—short version (SELSA) The SELSA consists of 15 items assessing emotional, family, and romantic loneliness rated on a 7-point Likert-type scale ranging from 1 ('strongly disagree') to 7 ('strongly agree'). It was found to have an internal consistency ranging from 0.87-0.90, to be significantly correlated with the long-established UCLA-Loneliness Scale, and has been extensively tested against other established measures (DiTommaso, Brannen & Best, 2004). Social and Emotional Loneliness is a secondary outcome.

Riding Diary (RD). The Riding Diary elicits participants' comments about the THR classes. It includes the date of the riding session, name of the horse ridden, and comments about the session. Veterans will complete the Riding Diary after each session. The diaries will enable

them to describe their THR experiences and record their feelings of THR mastery. These data will address Research Question #2.

J. Test Procedures. After participants' consent and Health Care Provider assent are obtained, we will conduct baseline data collection comprising the DQ, HH, PCL-M, CSES, DERS, and SELSA. Participants will be informed to which group they have been randomly assigned. Those assigned to the RG will attend THR classes at the PATH-Accredited Riding Stable study site geographically closest to their homes. Those assigned to the CG will be informed that they will be able to begin THR classes in approximately 8 weeks. We will conduct data collection again 3 weeks and 6 weeks later for all participants.

The RG will go to their respective THR site to undergo an assessment by an Occupational Therapist to ascertain their needs to ensure safety during THR, and to identify which horse will be assigned to each rider. Once completed, participants will attend THR classes once per week for 6 weeks in accordance with the THR Curriculum (see attachment). THR classes will consist of time to groom and interact with the horse and supervised riding with a horse leader and sidewalkers as needed to ensure safety, all supervised by the Occupational Therapist. All leaders, and side walkers will be trained for their roles in accordance with the PATH requirements.

K. Data Analysis Plan. The statistician (Dr. Pak) will perform data analysis after data collection and entry. For accuracy, double data entry will be employed. The two data sets will be compared. Discrepancies will be corrected using the primary sources.

For testing Hypothesis 1, a two sample t-test will compare changes in primary and secondary outcome variables (overall CSES, total PCL-M score, etc.) between the two groups. To establish a predictive model, a mixed model will be used for each outcome variable using time (baseline, 3 weeks, 6 weeks) and group as within and between group variables, respectively along with potential confounding variables as covariates. The set of covariates will be determined if a third

variable such as a demographic or health history variable is significantly associated with both the outcome and the group variables. The SAS PROC Mixed Procedure will be used for the mixed model since it is known to be robust for missing values. The MIXED procedure allows us to model the correlation between the repeated measures over time in a variety of ways, the simplest being autocorrelation of order 1 (AR1). Of primary interest in this analysis is the Group main effect or the Group by Time interaction. Least Squares Means (LSMeans) can be used to compare groups. Residuals from this model will be examined for normality. If residuals show non-normality, nonparametric methods such as the Wilcoxon Rank Sum test or Cochran-Mantel-Haenszel (CMH) test will be used for analysis. To test Hypothesis 2, a correlation between changes in each outcome variable and the number of THR sessions will be investigated using Pearson's or Spearman's correlation coefficients. Basic descriptive statistics including the range, mean, median, and standard deviation, will summarize demographic and baseline data. Analyses will be conducted under the intention-to-treat principle (all participants randomized to a group will be included in the analysis regardless of their level of participation). SAS 9.3 will be used for all data analyses (SAS Institute Inc., Cary, NC, USA).

- V. Proposed Time Line: Please see Appendix Table 1.
- VI. Intent to Present/Publish. The multi-disciplinary collaboration in the research team will enable presentation of findings at a robust array of regional, national and international conferences including but not limited to: Society for Social Work and Research, Midwest Symposium on Therapeutic Recreation and Adapted Physical Activity, American Therapeutic Recreation Association, International Association of Human-Animal Interaction Organizations, American Public Health Association, Midwest Nursing Research Society, and the American Psychological Association. We will target publications for the following peer-reviewed journals: Military Behavioral Health, Federal Practitioner, U.S. Medicine, Research on Social Work Practice, Therapeutic Recreation Journal, Traumatology: An International Journal, and Anthrozoos.

VII. Proposed Budget

Item	Cost	Totals
PERSONNEL:	% (Salary + Fringe)	
(Company)	40/10000000	
40 drahabarday		
	40000000000000000000000000000000000000	
·		
· · · · · · · · · · · · · · · · · · ·	man humandand	
PERMANENT EQUIPMENT:		0.00
CONSUMABLE SUPPLIES:		
Bottled water	\$4.00 each x 10 cases	40.00
T-shirts (16 staff & 40 participants)	\$6.50 each x 56 shirts	364.00
Lapel pins	\$2.00 each x 40	80.00
Poster for scientific meetings	4 posters x \$54 each	216.00
CONSULTANTS:		
D. Albright		0.00
C. Crompton		0.00
K. Scholl		0.00
B. McGavock		0.00
TRAVEL:		
Staff training (one-day meeting at	STL sites travel to Columbia (250 miles x	262.00
ReCHAI)	52.5cents)=\$131.25x 2	
	Food for 16 at \$15 each	245.00
OI HAIR DEL AREA EXPENIONO		
CLIENT-RELATED EXPENSES:	0.000.00	
Participant THR Tuition	\$600.00 each per 6 week session—	24,000.00
	For 40 participants	
HORSE EXPENSE:		0.00
TOTAL REQUESTED		\$50,000.00

VIII. Budget Justification

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 and 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.

Rebecca A. Johnson, PhD, RN, FAAN: (Bio attached) Dr. Johnson will devote 2% of her time on this project as Principal Investigator (PI). She will be responsible for all matters relating to conduct of the study including study staff training, protocol implementation, intervention fidelity, data collection, interpretation, and selection of dissemination outlets for findings.

Youngju Pak, PhD: Assistant Professor, Dept. of Biostatistics, University of Missouri, Columbia, MO. Dr. Pak has extensive experience in design and implementation of data analytic plans for intervention research. She will be responsible for data spreadsheet preparation, data cleaning and all statistical analysis. Dr. Pak will devote 5% of her time on this project as statistician.

Personnel Total: \$24,793.00

Personnel % of total budget: 50%

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

Permanent Equipment Total: \$0 Permanent Equipment % of total budget: 0%

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

Bottled water, t-shirts for staff and participants, lapel pins. Posters for scientific meetings.

Consumable Supplies Total: \$700.00

Consumable Supplies % of total budget: 1%

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

Unpaid Consultants (all have provided input into the grant application)

David Albright, PhD, MSW; Director, Center for Education and Research for Veterans and Military Families, MU School of Social Work, Columbia, MO. Dr. Albright will provide assistance should study family or community issues arise with participants. As a veteran and social worker, he is fully acquainted with issues associated with community readjustment. This will ensure that participants' needs are met and that the study progresses smoothly.

Constance Crompton, OT; Occupational Therapy/ Rehabilitation Services, University of

Missouri Health Care, Columbia, MO. Ms. Crompton will oversee Therapeutic Horseback Riding protocols and lessons at the Cedar Creek Therapeutic Riding Center, Columbia, MO. However in her role as consultant, she will assist with lesson plan training of riding center staff in the three study sites, which is essential to ensure intervention fidelity.

Kim Scholl, PT; Physical Therapist at Renaissance Therapy, Columbia, MO. Ms. Scholl will consult on physical functioning/rehabilitation issues arising with the study participants.

Brenda McGavock, PhD; Psychologist, Fletcher and McGavock, clinical Psychologists, Columbia, MO. Dr. McGavock will provide consultation for any psychological issues arising with study participants. This will ensure that participants' needs are met and that the study progresses smoothly.

Consultant Costs Total: \$0.00

Consultant Costs % of total budget: 0%

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

Travel Costs Total: \$507.00

Travel % of total Budget: 1%

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

Tuition costs (\$600.00 per participant) for the Therapeutic Horseback Riding program.

Client-Related Expenses Total: \$ 24,000.00

Client-Related Expenses % of total budget: 48%

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

NONE

Horse Expense Total: \$ 0.00

Horse Expenses % of total budget: None

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

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.

Total Active/Committed: \$ None

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.

Total Pending: \$ None

RA Johnson

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 for your salary, funding for your research, and inclusive funding dates.

Total Related Support: \$ None

IX. Lay-language Abstract

Importance: U.S. military veterans have made great sacrifices for their country. After combat deployment, very large numbers of them suffer Post Traumatic Stress Disorder and Traumatic Brain Injury. These conditions make it extremely difficult for the veterans to readjust to civilian life. They feel very anxious, have flashbacks, and have trouble feeling positive emotions. They may have memory loss, trouble understanding complex tasks, and solving problems that they encounter in daily life. They may also have daily physical pain from combat injuries. Research so far is promising that therapeutic horseback riding can help people with such physical, emotional, and cognitive challenges. But no studies of veterans have been done.

Plan: Our proposed study will test the effectiveness of a 6-week human-horse interaction and therapeutic horseback riding program in decreasing Post-Traumatic Stress symptoms and increasing belief in their ability to cope, positive mood, and social engagement among 40 previously deployed U.S. military veterans. Participants will be over age 18 years, weigh under 250 pounds, and be able to walk 25 feet independently (or with an assistive device), who consent to participate and whose Health Care Provider agrees. Those randomly assigned (through a computer program that creates two study groups) to the Riding Group will spend one hour per week interacting with and riding the same horse at one of three PATH-accredited riding centers in Mid-Missouri under the supervision of an Occupational Therapist. Veterans will be guided by a PATH-certified instructor, a leader and have side walkers as needed to ensure safety. Riding will be directed by a systematic lesson plan. We will assess these participants when they enter the study, after 3 weeks of riding, and again after 6 weeks of riding.

Veterans randomly assigned to the Control Group will be assessed when they enter the study, and 3 and 6 weeks later while they wait to switch to the Riding Group.

Team: We are a strong research team led by a professor of nursing and veterinary medicine who has a strong track record of research success, and who is presently doing another study with

veterans. Because the problem for veterans is complex, our team has a mental health nurse practitioner, doctor, psychologist, social worker, occupational therapists, a recreation therapist, PATH-certified riding instructors, and research assistants who will work together to be sure that our study is excellent. We will present and publish the results to share what we learn.

X. Bio-Sketch of PI

BIOGRAPHICAL SKETCH

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

NAME	POSITION	TITLE	
Johnson, Rebecca A.	Professor		
eRA COMMONS USER NAME		nool of Nursing	
_JohnsonR A	University of	of Missouri	
EDUCATION/TRAINING (Begin with baccala	ureate or other ini	tial professiona	al education, such as
	DEGREE		
INSTITUTION AND LOCATION	(if	YEAR(s)	FIELD OF STUDY
	applicable)		
		40=0	** .

INSTITUTION AND LOCATION	(if	YEAR(s)	FIELD OF STUDY
	applicable)		
Rock Valley College, Rockford, IL	AAS	1978	Nursing
University of Dubuque, Dubuque, IA	BSN	1980	Nursing
University of Edinburgh, Edinburgh Scotland, UK	MPhil	1982	Nursing
University of Iowa, Iowa City, IA	MA	1988	Adult Health Nursing
University of Iowa, Iowa, City, IA	PhD	1992	Gerontological Nursing

A. Personal Statement

The goal of my program of research is to study the clinical outcomes of human-companion animal interventions in vulnerable populations, most notably older adults and veterans. The clinical outcomes that are most compelling for this line of research are psychosocial outcomes resultant from the unconditional love and support provided by interaction with companion animals.

I have a successful track record of intramural, NIH, and other extramural funding for my research. My research uses of innovative, realistic, community-based, descriptive and experimental designs merging older adults with companion animals. Current and recent projects test HAI interventions among veterans who have physical (pain) and psychosocial (PTSD/TBI) challenges.

Holding joint faculty appointments in nursing and veterinary medicine, I am director of the collaborative Research Center for Human Animal Interaction, where I supervise one full-time and five part-time staff in addition to veterinary medical student research mentees, and doctoral students. I serve on HAI doctoral dissertation committees outside of the University of MO, was an external examiner for 2 international HAI dissertations, and have served as major advisor for 5 doctoral students at MO.

B. Positions and Honors

Professional	Experience:

1982	Hospital Staff RN, Southwest Health Center, Cuba City, WI
1982-1983	Nursing Home Staff RN, Southwest Health Center, Cuba City, WI
1983	Nursing Home Supervisor, Southwest Health Center, Cuba City, WI
1983-1984	Instructor/Research Coordinator, Finley Hospital School of Nursing, Dubuque, IA
1984-1987	Instructor, Finley Hospital School of Nursing, Dubuque, IA
1986-1988	Lecturer, College of Nursing, University of Iowa, Iowa City, IA
1987	Adjunct Faculty/Nursing Research, University of Dubuque, IA

RA Johnson

	RA Johnson
1987-1991	Staff Nurse/Medical-Surgical Staff Pool, Mercy Health Center, Dubuque, IA
1992-1999	Assistant Professor, School of Nursing, Northern IL University, DeKalb, IL
1998-1999	Associate Professor, School of Nursing, Northern IL University, DeKalb, IL
1999-2011	Associate Professor, Sinclair School of Nursing, University of MO, Columbia,
	MO
2000-2011	Associate Professor, Department of Veterinary Medicine and Surgery, College of
	Veterinary Medicine, University of MO, Columbia, MO
2005-present	Director, Research Center for Human Animal Interaction, College of Veterinary
	Medicine, University of MO, Columbia, MO
2012-present	Professor, Sinclair School of Nursing and, Department of Veterinary Medicine
	and Surgery, College of Veterinary Medicine, University of MO, Columbia, MO
Honors and A	wards
1987	Inducted into Sigma Theta Tau, Gamma Chapter, International Nursing Honor
	Society, University of IA, Iowa City, IA
1989	Pre-Doctoral Fellowship from the National Institutes of Health, Center for
	Nursing Research
1989	"Starshine Award" for "vision, innovation, and enthusiasm", Gamma Chapter,
	Sigma Theta Tau International Nursing Honor Society, University of IA
1996	Excellence in Undergraduate Teaching Award, School of Nursing, Northern IL
	University
1997	Excellence in Undergraduate Teaching Award, School of Nursing, Northern IL
	University
2001	Gerontological Nursing Research Award, Midwest Nursing Research Society
2001	Inducted into Alumni Hall of Fame, Rock Valley College, Rockford, IL
2001	Excellence in Teaching Award, Sinclair School of Nursing, University of MO,
	Columbia, MO
2002	Excellence in Research Award, Sinclair School of Nursing, University of MO,
2002	Columbia, MO
2003	Distinguished Alumni Achievement Award, College of Nursing, University of IA
2005	William T. Byler Distinguished Professor Award, University of MO, Columbia,
• • • •	MO
2007	Inducted as a Fellow, American Academy of Nursing (FAAN)
2008	Inducted into Phi Zeta, Veterinary Medicine Honor Society
2009	Humane Society of the US, 11 th Annual "Animals and Society" Distinguished
	Established Course Award for Psych 2830: Human-Companion Animal
	Interaction
2010	Excellence in Service Award, Sinclair School of Nursing, University of MO,
	Columbia, MO

C. Selected Publications

- 1. Smarr, K.L., Musser, D.R., Shigaki, C.L., Johnson, R. A., Hanson, K.D., & Chokkalingam, S. (2011). Online self-management in rheumatoid arthritis: a patient-centered model application. *Telemedicine & e-Health*, 17(2), 104-110.
- 2. Johnson, R. A., Beck, A. M., & McCune, S. (2011). The Health Benefits of Dog Walking for Pets and People: Evidence & Case Studies. West Lafayette, IN: Purdue University Press.
- 3. Zeltzman, P. & Johnson, R. A. (2011). Walk a Hound, Lose a Pound: How You & Your Dog Can Lose Weight, Stay Fit, & Have Fun Together. West Lafayette, IN: Purdue University Press.

- 4. Johnson, R. A., Radina, M., & Popejoy, L. (2010). Older adults' participation in nursing home placement decisions. *Clinical Nursing Research*, 19(4), 358-375. doi: 10.1177/1054773810372990.
- 5. Johnson, R. A., & Meadows, R. L. (2010). Dog-Walking: Motivation for adherence to a walking program. *Clinical Nursing Research*, 19(4), 387-402. PMID: 20651066
- 6. Johnson, R. A. (2011). Human animal interaction and animal assisted therapy. In R. Davis (Ed.), *Caring for family pets: Choosing and keeping our companion animals healthy*, Ch 3. New York, NY: Praeger Publishers, an imprint of ABC-CLIO.
- 7. Johnson, R. A. (2010). Animal assisted Interventions in human healthcare. In P. McCardle, S. McCune, J. Griffin & L. Esposito (Eds.), *How Animals Affect Us: Examining the Influence of Human-Animal Interaction on Child Development and Human Health*, Ch 9. Washington, D.C.: American Psychological Association.
- 8. Baun, M. M., & Johnson, R. A. (2010). Human animal interaction and successful aging. In A. Fine (Ed.), *Handbook on Animal Assisted Therapy: Theoretical Foundations and Guidelines for Practice* (pp. 283-299). New York, NY: Elsevier.
- 9. Johnson, R. A. (2010). Psychosocial & therapeutic aspects of human-animal interaction. In P. Rabinowitz, & L. Conti (Eds.), *Human-animal medicine; Clinical approaches to zoonoses, toxicants, and other shared health risks* (pp. 24-36). Maryland Heights, MO: Saunders, an imprint of Elsevier, Inc.
- 10. Johnson, R. A., Rantz, M. J., McKenney, C. A., & Cline, K. M. (2008). TigerPlace: Training veterinarians about animal companionship for the elderly. *Journal of Veterinary Medical Education*, 35(4), 511-513. PMID: 19228901
- 11. McKenney, C., & Johnson, R. A. (2008). Unleash the healing power of pet therapy. *American Nurse Today*, *3*(5), 29-31.
- 12. Rantz, M., Porter, R., Chesier, D., Otto, D., Servey, C., Johnson, R. A., Aud, M., Skubic, M. Tyrer, H., He, Z., Demiris, G., Alexander, G., & Taylor, G. (2008). TigerPlace, a state-academic-private project to revolutionize traditional long-term care. *Journal of Housing for the Elderly*, 22(1/2), 66-85.
- 13. Johnson, R. A., & Gayer, A. (2008). Puppy love for older adults. *Journal of Gerontological Nursing*, 34(1), 52-53. PMID: 18274305
- 14. Johnson, R. A., Meadows, R., Haubner, J., & Sevedge, K. (2008). Animal assisted activity with cancer patients: Effects on mood, fatigue, self-perceived health and sense of coherence. *Oncology Nursing Forum*, *35*(2), 225-232. PMID: 1832183
- Smarr, K. L., Siva, C., Johnson, R.A., Donovan Hanson, K., Musser, D. R., Hewett, J. E., Ge, B., Parker, J. C. (2007). Online self-management program in rheumatoid arthritis: RAHelp.org 3-month analysis. *Arthritis and Rheumatism*, 56(9 Supplement), S308.
- 16. Harnirattisai, T., Johnson, R. A., & Kawinwonggowit, V. (2006). Evaluating functional activity in older Thai adults. *Rehabilitation Nursing*, 32(3), 126-130.
- 17. Harnirattisai, T. & Johnson, R. A. (2005). Effectiveness of a behavioral change intervention in Thai elders after knee replacement. *Nursing Research*, 54(2), 2-12.
- 18. Rantz, M. J., Marek, K. D., Aud, M.A., Johnson, R. A., Otto, D., & Porter, R. (2005). TigerPlace: A new future for older adults. *Journal of Nursing Care Quality*, 20(1), 1-4.
- 19. Johnson, R. A. (Special Issue Guest Editor). (2003). Human-animal interaction and wellness. *American Behavioral Scientist*, 47(1), 5-102.
- 20. Johnson, R.A., Meadows, R. L., Haubner, J. S., & Sevedge, K. (2003). Human-animal interaction: A complementary/alternative medical intervention (CAM) for cancer patients. *American Behavioral Scientist*, 47(1), 55-69.
- Johnson, R. A., & Meadows, R. (2002). Older Latinos, pets and health. Western Journal of Nursing Research, 24(6), 609-620. PMID: 12365763

- 22. Johnson, R. A., Odendaal, J., & Meadows, R. (2002). Animal assisted interventions research: Issues and answers. *Western Journal of Nursing Research*, 24(4), 422-440. PMID: 12035914
- 23. Johnson, R. A. (Special Issue Guest Editor). (2002). Human-animal interaction research. *Western Journal of Nursing Research*, 24(6), 606-715.
- 24. Johnson, R. A., & Tripp-Reimer, T. (2001). Aging, ethnicity and social support: A review. *Journal of Gerontological Nursing*, 27(6), 15-21.
- 25. Johnson, R. A., & Tripp-Reimer, T. (2001). Relocation among ethnic elders: A review. *Journal of Gerontological Nursing*, 27(6), 22-27.

D. Research Support

Ongoing

(Johnson)

11-2011-present

NIH/NICHD 1R03HD070557-01

Dog presence and children's stress during forensic interviews for child abuse.

Two-group randomized controlled trial testing effects of presence of a service dog on children's stress during forensic interviews for child abuse.

(Johnson)

6/2011-present

University of Missouri, Mizzou Advantage Seed Grant

Puppies for parole: Shelter dog training and inmate behavior outcomes

Two-group experiment testing effects of caring for and training shelter dogs on self-esteem, locus of control, requests for medical services, and self-perceived physical and emotional health in prison inmates.

(Johnson)

10/2010-present

Waltham Pet Nutrition Research Centre, Banfield Charitable Trust, Pedigree Foundation, & University of Missouri Research Board

Veterans and shelter dogs: Mutual enrichment

Two-group delayed treatment design testing association between training shelter dogs basic obedience and Post-Traumatic Stress Disorder symptoms, mood and family adjustment in US veterans.

(Johnson)

06/2009-12/2011

International Society for Anthrozoology & Waltham Pet Nutrition Research Centre Seniors fostering shelter dogs: Improving health and well-being together

Two-group delayed treatment design testing association between providing foster care to shelter dogs and physical functioning, physical activity, mood, self-perceived health, and social support among older adults.

Completed

(Johnson)

07/2009-12/2011

Waltham Pet Nutrition Research Centre

Caring for both ends of the leash: Effects of owners visiting their dogs hospitalized in an Intensive Care Unit

Describe clinical outcomes (heart rate, blood pressure and pain) in dogs whose owners visit them in the veterinary medical teaching hospital.

(Johnson)

NIH/NICHD 1R13HD062078-01

10/2009

Research meets practice: Human-animal interaction in obesity across the lifespan

Symposium (10/23/09) fostering dialogue between investigators and health care practitioners.

(Johnson)

10/2007-10/2009

Waltham Pet Nutrition Research Centre

Walk a hound, lose a pound, and stay fit for older adults

Three-arm trial testing impact of walking shelter dogs, a human companion, or maintaining usual activities on older adults' physical function, activity, weight, physical activity stage of change, mood & social support.

(Johnson)

4/2007-12/2009

Li'l Red Foundation

PALS for seniors animal assisted activity training & certification

Online training program for people to prepare themselves and their dog to do community, hospital and/or nursing home Animal Assisted Activity visits with older adults.

(Johnson)

09/2007-09/2008

Missouri Foundation for Health

Ask the community: Barriers & facilitators to exercise

Identified barriers & facilitators to exercise among intergenerational families residing in public housing.

(Parker, PI with Smarr, Walker, Johnson, Co-I, & Childers)

6/2003-

12/2008

National Institute on Disability and Rehabilitation Research

An online self-management program for older adults with rheumatoid arthritis.

Investigated efficacy of online self management of chronic symptoms and support platforms (education modules, self-monitoring, online discussion, and online access to therapist).

(Johnson)

12/2005-11/2006

University of Missouri Research Board Council Grant.

Testing a dog visit protocol with newly admitted nursing home residents.

Three-arm randomized trial comparing effects of dog visits, friendly human visits, and usual care on loneliness and salivary cortisol levels of older adults admitted to a nursing home within one month.

(Johnson)

09/1999 - 07/2005

NINR R29 5R29NR004435-04

Relocation of ethnic elders: Decisions and sequelae

Identified decision-making processes and support sources when older adults relocate to a nursing home.

(Johnson, PI with Meadows, R)

1/2002-12/2004

Missouri Foundation for Health.

Walking for healthy hearts.

Pre-test post-test design testing efficacy of and adherence to graduated dog walking intervention on weight in sedentary, older adult residents of public housing.

(Johnson, PI with Sevedge, K., & Meadows, R.)

08/2000 - 05/2002

University of Missouri Comprehensive Cancer Center

Animal assisted activity and anxiety among radiation therapy patients

Three-arm randomized pilot trial testing effect of quiet interactions with a visitor dog, a friendly person, or quiet reading on mood in cancer patients undergoing radiation therapy.

(Johnson)

1/2000-12/2000

Gerontological Nursing Interventions Research Center, University of Iowa.

Ethnic elders, pet attachment, health, and well-being.

Identified importance of companion animals on health and well-being among African American, Latino, and Caucasian older adults.

XI. Evidence of Compliance with Government Requirements

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 Curators of the University of Missouri (Applicant Institution) agrees that if a research grant is awarded by the Horses and Humans Research Foundation (HHRF) to Rebecca A. Johnson (Applicant/Principal Investigator) for the project "Therapeutic Horsemanship for Veterans (ToRCH for 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 Missouri, the University of Missouri (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

Karen M Jeren Signature

Karen M. Geren, Submissions Specialist - Authorized Signer

10 31 2012 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 Curators of the University of Missouri (Applicant Institution) agrees that if a research grant is awarded by the Horses & Humans Research Foundation (HHF) to Rebecca A. Johnson (Applicant or Principal Investigator) for the project Therapeutic Horsemanship for Veterans (ToRCH for 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 Missouri, the University of Missouri (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

Karen M. Geren Signature

Karen M. Geren, Submissions Specialist - Authorized Signer

10 31 2012 Date

XII. 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:	
Principal Investigator's signature:	Date:
Principal Investigator's name and title (please print)	
Rebecca Johnson, PhD, RN, FAAN Millsap Professor of Gerontological Nursing MU Sinclair School of Nursing Professor & Director, Research Center for Human Animal Interaction MU College of Veterinary Medicine	
Signed on behalf of The Curators of the University of Missouri:	
Karen my Geren	Date: 10 31 2012
Karen M. Geren, Submissions Specialist - Authorized Signer	

XIII. Attachments

Table Of Contents

References

Curriculum

Riding Arena Set Up

Table 1: Project Timeline

Table 2: Data Analysis Plan

Table 3: Protection of Participants and Horses

Table 4: Participant Enrollment

Instruments:

Inclusion/Exclusion Form

Demographic Quesionnaire

Health History

Coping Sefl Efficacy Scale (CSES)

PTSD Checklist – Military Version (PCL-M)

Difficulation in Emotion Regulation Scale (DERS)

Social and Emotional Loneliness Scale for Adults- short version (SELSA)

Riding Diary (RD)

Data Collecgtion Sheet for Research Assistant (RA)

Job Descriptions

Project Coordinator

Research Assistant

Horse Leaders

Side Walkders

Letters of Support

Therapeutic Horsemanship

Ride on St. Louis

Cedar Creek Therapeutic Riding Center

Annette Sobel

Carol Fleisher

Judith Fitzgerald Miller

John R. Dodam

Cynthia L. Russell

Youngju Pak

David Albright

Constance Crumpton

Kim Scholl

Brenda McGavock