I. HHRF RESEARCH GRANT APPLICATION COVER LETTER

Title of Project: Psychophysiological effects of Equine-assisted therapy on horses and in veterans diagnosed with post-traumatic stress disorder (PTSD)

Submission Date: August 1, 2019

Principal Investigator Name and Title: Laurie McDuffee, DVM, PhD, DACVS, Professor of Large Animal Surgery, Atlantic Veterinary College, University of Prince Edward Island

Contact Name and Title: Laurie McDuffee, Professor of Large Animal Surgery

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Describe your methodology: Prospective Cohort study

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

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:

Serene View Ranch, 174 Pickles Ln, Websters Corner, PE

- Caroline Leblanc, Registered Psychologist, EAGALA-Equine-assisted Growth and Learning Association

- Emily Hart, Equine Specialist, EAGALA-Equine-assisted Growth and Learning Association

Are all listed personnel certified to provide the activities?

Yes

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

Equine-assisted Growth and Learning Association, EQUINE@EAGALA.ORG, PO BOX 993, SANTAQUIN, UT 84655 USA, 1-801-754-0400

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:

- Researchers at the University of Prince Edward Island will lead the research, which will be conducted in collaboration with specialists and clients at Serene View Ranch (see letter of support in attachments).

Brief description of project (60 words or less): The purpose of this project is to explore the efficacy of equine facilitated psychotherapy (EFP) on human-horse dyads through changes in measures of stress hormones and PTSD symptoms. The study uses a prospective cohort design consisting of an 8-week EFP intervention for combat veterans with PTSD. The study is novel in the representation of paired data from the human-horse dyad.

Pilot Study Completed? Yes **Completion Date**: May 2019

Is project Institutional Review Board approved? Pending

Please attach a copy of the IRB application (see attachment for UPEI IRB Review, including letter of informed consent). Evidence of final IRB approval must be presented to HHRF prior to the start date of the project.

Planned Start Date of Project: January 1, 2020 **End Date of Project**: June 30, 2021

Amount Requested from HHRF: $46,805

II. SCIENTIFIC ABSTRACT

As a necessary step in demonstrating the benefits of equine facilitated psychotherapy (EFP) as a positive treatment for veterans with PTSD, while eschewing the development of an adverse environment for either humans or horses, this study aims to obtain objective and subjective data from selected tests on the human-horse dyad. Efficacy of EFP on human-horse dyads will be determined through changes in measures of stress hormones: cortisol and oxytocin, and changes in heartrate variability in horse and human participants, concomitantly. Cortisol and oxytocin will be obtained in humans from passive drool, and from saliva and blood samples in horses. HRV measures will obtained from Polar HR monitors worn by horses and humans. PTSD symptoms based on the Beck Depression Inventory (BDI 2), the State Anger Scale (STAXI 2), and the Checklist: PCL-5 will be used to provide trait-based psychometric estimates, while behavioral indicators of stress in horses will be based on expert ratings using the BORIS system. The proposed analysis is novel in the representation of paired data from the human-horse dyad. Evaluation of entrainment, which we define operationally as the synchronization of selected physiological measures between the human-horse dyad during EFP will be assessed through Bland-Altman measures of agreement.

III. NEED/JUSTIFICATION

Post-traumatic stress disorder (PTSD) is a psychiatric disorder that occurs in persons after experiencing or witnessing a traumatic event (APA, 2017). The condition is characterized by intrusive thoughts, avoidance, negative thoughts and feelings, and over arousal (APA, 2013), and is associated with numerous comorbidities (Krondish et al., 2012; Park et al., 2017) including depression (Bersani et al., 2016); anxiety (Church et al., 2018); chronic pain (Otis et al., 2013); hypertension (Moazen-Zadeg et al., 2016); and substance abuse-related issues (Johnson et al., 2016). PTSD can be a chronic and disabling condition, affecting all areas of a person's well-being (Bhatnager et al., 2013). Although observed across the general population (Kilpatrick et al., 2013), PTSD is particularly prevalent in military veterans who have been exposed to combat duties (Hines et al., 2014; Stevelink et al., 2018).

Veterans with PTSD often struggle with emotion and impulse control resulting in the inability to appropriately handle even minimal stress and leading to physiological dysregulation (Jerg-Bretzke et al., 2013; Mozaen-Zadeh et al., 2016). PTSD is marked by increased sympathetic activation and decreased parasympathetic responses in the autonomic nervous system (ANS), which can cause disruptions in heart rate variability (HRV) (Cohen et al., 2000). HRV is an objective physiological parameter used to assess and monitor variation in heartbeat intervals (Acharya et al., 2006) and is a non-invasive method of assessing the autonomic system (Bhatnager et al., 2013). Studies investigating HRV in veterans with PTSD have shown that individuals often demonstrate lower HRV than the general population (Park et al., 2017). Low HRV is indicative of an ANS system in state of perpetual fight-or-flight mode, which is associated with many mental and physical conditions (Campos, 2017). Changes in HRV have been noted to correlate with changes in PTSD symptoms, as measured by the Clinical

Administered PTSD Scale (CAPS), suggesting that HRV may be a biomarker of disease and treatment response (Bhatnager et al., 2013).

PTSD has been associated with medication non-adherence (Wasson et al., 2018), which is posited to increase mortality rates in patients living with the diagnosis (Krondish et al., 2012). Moreover, previous investigations into the use of medication for treatment of PTSD have shown that medical intervention alone may not be sufficient (Mann & George, 2017). This observed limitation to clinical treatments has led to numerous attempts to evaluate alternative, non-medical interventions such as animal assisted therapy (AAT).

Animal assisted therapy (AAT) in veterans with PTSD

Animal assisted therapy (AAT) is used to promote the mental and physical health of humans (O'Haire, Guerin & Kirkham, 2015). Previous studies using animal assisted therapies for veterans with PTSD have demonstrated positive effects on symptoms of PTSD (Wortman et al., 2018) and comorbidities, such as anxiety and depression (O'Haire, Guerin & Kirkham, 2015; van Houtert et al., 2018). One particular field of interest is the use of equine assisted activities and therapies (EAA/T) for treatment of PTSD in military veterans. Horses provide a unique therapeutic experience for veterans diagnosed with PTSD due to their large size and nature as a prey animal. The interaction between veterans and horses can help participants improve communication skills and confidence in a way that appeals to the veteran’s sense of adventure and achievement (Masini, 2010; Latella & Abrams, 2015).

Veterans report seeking participation in equine-assisted activities due to feelings of helplessness and hopelessness, as well as a desire to seek social connections (Lanning & Krenek, 2013). Horses communicate primarily through body language (Lentini & Knox, 2009) and respond to humans' emotions and behaviors (Burgon, 2011; Karol, 2007; Latella &

Abrams, 2015). It is believed that these qualities of the horse facilitate the therapeutic effect by allowing humans to identify with the horses' natural instinct to seek safety and security (Latella & Abrams, 2015; Masini, 2010). Veterans with PTSD interact with horses through mounted and unmounted activities to work through concerns in a natural and physically challenging environment (Latella & Abrams, 2015).

Equine assisted interventions are characterized by a unique environment outside of the typical office setting. Previous investigations on non-medical interventions have shown that veterans with PTSD may benefit from participation from outdoor recreational activities through increases in well-being and decreases in symptoms of PTSD (Bhatnagar et al., 2013; Church et al., 2018; Jasbi et al., 2018; Vella, Milligan & Bennett, 2013). Physical exercise (Shivakumar et al., 2017; Whitworth & Ciccolo, 2016) and leisure functioning (Johnson et al., 2016) are also believed to contribute to the success of EAA/T in reducing symptoms of PTSD.

Evaluation of EFP in veterans with PTSD

Empirical evidence on the use of horses to treat PTSD symptoms in veterans is conflicting, perhaps owing to a low level of methodological standardization and rigor across studies (O'Haire, Guerin & Kirkham, 2015). Use of horses for treatment of PTSD has been shown to be effective at decreasing the impact of symptoms (Malinowski et al., 2018) through activities such as grooming, leading, and riding the horse with the goal of improving muscle function and coordination; increasing communication skills; and decreasing stress (Lanning & Krenek, 2013). Similarly, Wharton and colleagues (2019) evaluated the impact of EFP through an activity designed to assist veterans in overcoming behaviors that play a role in combat-related trauma (e.g. force versus coercion). The equine assisted activity (EAA) of interest involved leading a horse without a rope or physical contact. Investigators observed significant

improvements from baseline on standardized assessments related to symptoms of PTSD and good working relationships, as determined by the Working Alliance Inventory (WAI) and Human Animal Bond Scale (HABS).

Despite these observed positive effects of EFP, some studies were not able to replicate findings. Burton and colleagues (2019), for example, did not find a significant impact of EFP in symptoms of PTSD. Symptoms in veterans receiving EFP were compared to a control group that received standard therapy for the treatment of PTSD. Both groups demonstrated an improvement in PTSD symptoms and decrease in cortisol levels, however, did not significantly differ from one another. These results suggest that although EFP was not superior to standard treatment, the use of horses for therapy provided similar results to standard PTSD therapy. The American Psychological Association (APA) recognizes two types of standard treatment for PTSD, including psychotherapy and pharmacotherapy (APA, 2017). Although EFP is not currently recognized by the APA as an evidence-based psychotherapy for PTSD treatment (APA, 2017), these findings suggest that use of therapy horses may be an alternative method of PTSD treatment that yields similar results. There is an expressed need for evaluation methods beyond self-perceived welfare of assisted humans in order to move towards standardization in scientific methodologies using objective measurement techniques (van Houtert et al., 2018).

Impact of EAA/T on horses

Although much research has been conducted on the assessment of EAA/T on humans, little is known about the effect of these interventions on the animals (O'Haire, Guerin & Kirkham, 2015). The lack of developmental standardization regarding the potential impact of the therapy on animal welfare poses potential risks to both animals and humans (van Houtert et al., 2018). In a systematic review on EAA, O'Haire and colleagues (2015) noted that no

outcomes related to animal welfare were reported in identified primary studies. Investigators argue that animal welfare is crucial to successful and ethical outcomes from human-animal interactions.

This need for a focus on animal welfare in EAA/T, such as EFP, is further emphasized in the Five Domain Model (Mellor, 2017). This framework describes five critical areas relevant to animal welfare assessment and management, including: nutrition; environment; health; behaviour; and mental state. Mental state of horses is a particularly important consideration in EFP for veterans with PTSD. Entrainment theory describes a process of mirroring in the interaction between independent mechanisms (Clayton, 2012), such as between the physiology of the horse and human during EFP. In other words, entrainment suggests that the functioning of a human's psychophysiology may have an effect on the health of the animal. This has led to concerns for the welfare of horses in EFP when the human participant has poor mental health, such as veterans with PTSD symptoms. Studies focusing on the potential impact of EFP on equine welfare has shown mixed findings; stress levels in horses, as measured by plasma cortisol concentrations and heart rate, have been shown to increase in some studies (Keeling, Jonare & Lanneborn, 2009) while remaining unchanged in others (Malinowski et al., 2018). Further research on the impact of EAA/T on animal welfare is needed to develop therapeutic understandings of the potential success of EFP (Wortman et al., 2018). Moreover, the available evidence on the use of EFP in persons that have experienced trauma, such as PTSD, suggests that it is a promising treatment option, however more research is needed (O'Haire, Guerin & Kirkham, 2015).

Current proposed analysis

The proposed study aims to build on previous research examining the impact of EFP on PTSD symptoms in veterans and fill the observed gap on animal welfare. In order for EFP to be a useful long-term treatment for veterans, researchers need to provide evidence that the therapy is beneficial to humans and is not adverse to the horses. The current study aims to obtain objective physiological and psychological data from veterans and horses that engage in EFP. Effect of therapy on humans and horses will be determined through cortisol as an indicator of stress, oxytocin as an indicator of stress modulation, the balance between the sympathetic and parasympathetic branches of the autonomic nervous system (e.g. through HRV); and by standardized assessment (humans) and behavioral indicators (horses) of stress. The proposed analysis is novel in the representation of paired data from the human-horse dyad.

IV. RESEARCH NARRATIVE

Novel contribution

This study will be innovative in its approach to studying the potential effects of EFP through a unique approach to data collection and analysis. Specifically, similar mixed methods data will be obtained from both human participants (i.e. veterans) and horses simultaneously to gain insight into the psychophysiological aspect of the human-horse dyad during therapy. Few investigations have explored the process of entrainment between humans and their horses, which posits that the physiological processes of humans and horses become rhythmically "in sync" with one another. The current study will examine this theory further and assess whether it contributes to any observed changes as a result of EFP in the human participants and horses.

Pilot work in the proposed area of study is ongoing. Recent publications and presentations by our research team include the determination of statistical reliability of heart rate variability in a sample of horses performing normal daily activities (walking, in cross-ties,

and standing in a box stall) (Mills et al, 2017; McDuffee, et al, 2019); evidence of stress during EAA among a sample of therapeutic riding horses in a CANTRA registered program (Carr, et al, 2019), and to determine stress among horses introduced to a teaching hospital (Hamza, et al, 2019). In these research studies our objective has been to establish the methodologies for scoring behaviours, assessing stress via salivary cortisol concentrations, and establishing the appropriate regimen for collecting and analyzing heart rate variability measures.

Research Question(s)

The central research question posed in the current study is: what is the effect on horses and humans when EFP is used as PTSD therapy for military veterans? Additionally, we aim to explore the influence of entrainment in the human-horse dyad as reflected in selected physiological measures.

Hypotheses

We hypothesize that humans will have a decrease in PTSD symptoms that will include a decrease in anxiety, anger and depression as measured by standardized psychological instruments, and corroborated through laboratory estimates of cortisol, oxytocin, and ANS responses determined by HRV. We further hypothesize that horses involved in EFP will be influenced to a measurable extent as a function of their participation.

- Hypothesis 1: Veterans will demonstrate a decrease in cortisol levels post intervention as compared to baseline testing
- Hypothesis 2: Veterans will demonstrate an increase in oxytocin levels post intervention as compared to baseline testing
- Hypothesis 3: Veterans will report an improvement in standardized psychological assessments of anxiety, depression, and anger

- Hypothesis 4: Levels of cortisol and oxytocin in horses participating in EFP will change post intervention as compared to baseline testing
- Hypothesis 5: Horses will demonstrate a decrease in observable stress behaviors as a function of their participation in EFP
- Hypothesis 6: Objectively collected data will demonstrate a synchronization between humans and horses

Design

The research design will consist of a prospective cohort study, comprised of 16 individuals, each matched with a therapy horse for the intervention period. In this design, the independent variable EFP, defined as one-hour therapeutic sessions consisting of grooming and leading the horse in a heated arena. The dependent variables include (1) four standardized psychological assessments measuring anxiety, depression, anger, and PTSD symptoms; and (2) physiological measures in humans and horses, as measured by salivary cortisol, oxytocin, and HRV. Covariables will include, but not be limited to: existing pharmacological regimens, sex of the human and horse, veterans' years of service, and age.

Methods

Participants

Sixteen veterans of the Canadian Armed Forces previously diagnosed with PTSD (4 groups of 4), recruited from Veterans Affairs Canada, will be enrolled in an 8-week program at Serene View Ranch, an EAGALA certified facility. Each veteran will be paired with an individual horse for the 8-week period. Ten healthy horses with experience as therapeutic horses, will be selected to participate in the study. The horses actively participate in a variety of EFP sessions year-round and are accustomed to the farm and the arena. During the study, the

horses will be kept in their usual management and husbandry routine. Horses will be matched to each veteran participant for 8 EFP sessions, 1 hour in duration. EFP sessions will involve grooming of horses and leading horses in an arena.

Measures

Measurement of symptoms of PTSD in veterans will be collected at three predesignated time points using four standardized surveys: the Multidimensional Anxiety Questionnaire (MAQ), the Beck Depression Inventory (BDI-II), and the STAXI-2 State Anger scale which assesses the intensity of anger as an emotional state at a particular time, and the PTSD Checklist (PCL-5) which is a 20-item self-administered assessment designed to measure symptoms of PSTD. The schedule for data collection will be prior to the first EFP session on day 1, after four sessions of EFP, and at the end of 8 sessions of EFP. In addition, veterans will complete a self-perceived well-being scale consisting of a 10 item scale ranging from unwell to well with verbal anchors at the start and end of each EFP session to evaluate state changes in mood.

Objective measurements of HRV, cortisol and oxytocin will be collected from human subjects using Polar Heart Rate Monitors and from passive drool samples, respectively. HRV data will be collected 30 minutes prior to each session during a resting period (baseline) and throughout each session. Specifically, heart rate monitor recording will be started when the monitors are placed on each individual 30 minutes before the therapy sessions begin, continued during the entire 1 hour EFP session, and for an additional 30 minutes after EFP, for a total of 2 hours. For each person, 10 minutes of HRV data before each session, 10 minutes during grooming of horses, 10 minutes at the midpoint of the time spent with the horses, 10 minutes during leading, and 10 minutes after the session will be collected for a total of five time periods

of HRV for analysis. Passive drool will be collected 30 minutes prior to each session during a resting period (baseline) and at the end of each session. Passive drool will be submitted to Salimetrics, LLC for cortisol and oxytocin analysis.

Horses will be instrumented with Polar Heart Rate monitors and will have saliva and blood samples collected for HRV, salivary cortisol and plasma oxytocin measures, respectively. Heart rate monitor recording will be started when the monitors are placed on each horse 30 minutes before the therapy sessions begin, continued during the entire 1 hour EFP session, and for an additional 30 minutes after EFP, for a total of 2 hours. For each horse, 10 minutes of HRV data before each session, 10 minutes during grooming, 10 minutes at the midpoint of the time spent with the veterans, 10 minutes while being led, and 10 minutes after the session will be collected for a total of five time periods of HRV for analysis.

Equine blood samples (10 mL) will be obtained via jugular venipuncture at rest, 30 minutes before the start of each session, and at the conclusion of the EAA/T session to measure plasma oxytocin. Equine saliva samples will be obtained with steri-swabs inserted into the corner of the horse's mouth at rest, 30 minutes before the start of each session, and at the conclusion of the EFP session to measure cortisol. To account for the diurnal rhythm fluctuations of cortisol, samples will be taken at approximately the same time each day. Positive reinforcement will be used during collection of blood and saliva so that horses do not become averse to the collection of samples. Plasma oxytocin will be determined using an Enzyme Immunoassay from Enzo Life Sciences, Inc. Salivary cortisol concentrations will be determined using an ELISA kit from Salimetrics previously validated for use in horses.

In addition, horses will be video recorded for 30 minutes before each session at rest (baseline) and during each session. Recordings will be evaluated for stress behaviors using

Behavioral Observation Research Interactive Software (BORIS). Five-minute segments of HRV data from humans and horses will be analyzed using Kubios software to determine HRV time and frequency domain measures.

Test Procedures and Testing Sites

This study is designed to measure and assess acute physiological changes in markers of stress and well-being in horses and humans as a result of participation in 8 EFP sessions with a registered psychologist and certified equine specialist. The study will be conducted at UPEI in partnership with Serene View Ranch. The EFP will take place at Serene View Ranch, which is accredited as a premier facility by EAGALA. Four humans and four horses will participate in the research project during each of 4 eight-week sessions. Humans and horses will data collected before and after each session during the 8 weeks of therapy.

A registered psychologist will oversee the EFP. Research personnel from the University of Prince Edward Island (Faculties of Science, Nursing, and the Atlantic Veterinary College) will collect data from humans and horses during the course of the therapy.

Analysis

Boris software will be used to evaluate equine stress behaviors observed during the sessions. In both human and horse participant, the Kubios software for HRV will be used to evaluate time and frequency domain measures that demonstrates autonomic nervous system responses. In saliva and blood sample drawn from the horse participants ELISA techniques will be used to assess concentrations of cortisol, while assessment of measures of oxytocin will be evaluated by Salimetrics Laboratories. Data will be analyzed using SAS to evaluate all physical and psychological measures such as plasma cortisol and oxytocin concentrations, as well as

HRV estimates (time-domain – meanHR, meanRR, SDNN; frequency-domain – LF/HF ratio) in both the horses and humans, and all pre- and post-survey measures.

V. PROPOSED TIMELINE: January 1, 2020 - August 31, 2020

- Group 1: Four Veterans and horses undergo 8 week EEA/T at Serene View Ranch.
- Group 2: Four Veterans and horses undergo 8 week EEA/T at Serene View Ranch.
- Group 3: Four Veterans and horses undergo 8 week EEA/T at Serene View Ranch.
- Group 4: Four Veterans and horses undergo 8 week EEA/T at Serene View Ranch.

Data collection will be ongoing, with data analysis to take place from September 2020 until February 2021. Manuscript writing and the presentation of findings is anticipated to take place from March to June 2021.

VI. INTENT TO PUBLISH

The research findings will be published in a peer reviewed journal such as The Journal of Military Veterans and Family Health, American Journal of Health Behavior, or Journal of Veterinary Behavior. In addition the knowledge dissemination will occur in the form of presentations at international conferences such as Canadian Institute for Military Veterans Health Research, International Society of Equitation Science, and International Veterinary Behavior Meeting.

VII. BUDGET

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): $ 46,805

1. PERSONNEL: (Principal investigator, co-investigator, statistician, research assistant)

Please describe scope of work, salary, fringe benefits, FTE

- **Animal Health Technician**: to assist in the equine related aspects of the research (instrumenting horses, saliva collection, blood collection, video recording)

  8 hours per week @ $30/hr x 32 weeks = 256 hours Total Cost: $7680.00

- **Laboratory Technician**: to process samples in the laboratory after all EAA/T sessions have been completed.

  8 hrs per week @ $30/hr x 26 weeks = 208 hrs Total Cost: $6240.00

- **Graduate Student Trainee:** to assist with equine and human instrumentation and data collection during EAA/T sessions as there will be 4 horses and 4 humans at each session

  4 hrs per week @ $20/hr x 32 weeks = 128 hrs Total Cost: $2688.00

Total Costs for Personnel: $ 16,608.00

Personnel % of total budget: 33%

2. PERMENANT EQUIPMENT:

Itemize and describe purpose, justification of needs, how it will be acquired, etc.

Total Costs for Permanent Equipment: $0.00

Permanent Equipment % of total budget: 0%

3. CONSUMABLE SUPPLIES:

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

- **Equine Salivary Cortisol ELISA:** 8 samples per session X 32 sessions = 256 samples

  7 ELISA kits @ $250 per kit. Total Cost: $2000

- **Steri swabs for collection of equine salivary cortisol** (256 samples)

  9 steri-swab kits at a cost of $107 plus tax per unit Total Cost: $1098

- **Equine blood oxytocin measures** 4 horses at 2 samples per session in 32 sessions, resulting in 256 samples to be run in triplicate. Requires 8 analysis kits with 5 at a group rate plus individual plates Total Cost: $3259.00

Total Costs for Consumable Supplies: $6357.00

Consumable Supplies % of total budget: 12.7%

4. THIRD PARTY ANALYSES:

- **Analysis of Salivary cortisol from human passive drool**

  Salimetrics, LLC 5962 La Place Court, Suite 275, Carlsbad, CA 92008

  4 individuals x 2 samples each x 32 weeks = 256 samples Total Cost: $11,620.00

- **Oxytocin from Human passive drool**

  4 individuals x 2 samples each x 32 weeks = 256 samples Total Cost: $11,620.00

Total Costs for Third Party Analyses: $23,240.00

Third Party Analyses % of total budget: 47%

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

- The working group will meet quarterly over the tenure of the project for a total of 6 meetings. Budgeted at $100.00 per meeting.

Total Costs for Travel: $600.00

Travel % of total budget: 1.2%

4. CLIENT-RELATED EXPENSES:

Itemize and describe all related costs.

Total Costs for Client-Related Expenses: $0.00

Client-Related Expenses % of total budget: 0%

5. HORSE EXPENSES: (Must be directly related to research question and methodology.)

Explain cost basis related to percentage of time used in project.

Total Costs for Horse Expenses: $0.00

Horse Expenses % of total budget: 0%

BUDGET JUSTIFICATION: No additional budget justification is applicable here.

A. PERSONNEL (non-paid research team members)

Laurie A. McDuffee, DVM, PhD, DACVS, will be responsible for overall study implementation and coordination, and will lead the equine aspect of the research. Dr. McDuffee is a Board Certified Large Animal Surgeon with 29 years of experience as an equine veterinarian and researcher. Her current research is focused on Comparative Wellness with an emphasis on horses.

William J. Montelpare, PhD, will be responsible for leading the human aspect of the research. Dr. Montelpare is a Research Chair in Human Development and Health, and has more than thirty years experience conducting studies in exercise science and human development, from a statistical, physiological, and epidemiological approach.

Caroline LeBlanc, Registered Psychologist, will lead the Equine-assisted Therapy. Caroline completed training in EMDR in 2013, Sensorimotor Psychotherapy and has been certified in Equine-assisted Psychotherapy, both with EAGALA and Natural Lifemanship. She now spends some of her clinical time in a horse arena, introducing the psychological benefits of horses to first responders, veterans and their families.

Angela Riveroll, PhD, will lead the laboratory aspects of the research. Dr. Riveroll earned her PhD in Microbiology and Immunology from Dalhousie University and then worked in Pharmaceutical and Biotechnology Industries in research, regulatory affairs and product development for 10 years. Dr. Riveroll's interests are based in translational health research, moving research from the "bench to bedside" and precision health, a proactive approach to health management across the lifespan that takes into account individual variability in gene sequence, gene expression levels, environmental exposures and lifestyle for each person.

James M. Thompson, MD, will assist with study design and interpretation of the findings. Following a clinical and research career in Family Medicine and Emergency Medicine, Dr. Thompson was the Research Medical Advisor at Veterans Affairs Canada for 14 years. He led the development of the well-being framework used at VAC, and published analyses of nationally representative surveys of the well-being of CAF veterans. He is adjunct Associate Professor in the Department of Public Health Sciences at Queens University, and the Research Medical Consultant at the Canadian Institute for Military and Veteran Health Research. He has over 100 scientific publications. He has special interests in the well-being of military veterans, particularly mental and physical health and disability, and the assessment of research evidence with respect to policy and services.

OTHER INCOME SOURCES and ANTICIPATED FUNDING SUPPORT:

a. Active/Committed: While not required, HHRF is interested to know if you have any matching funds to support this grant if awarded (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: $ 0

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: $ 0

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.

Canadian Institute of Health Research , April 1, 2018 – March 31, 2023

Project Title: The Aging, Community and Health Research Unit – Diabetes Community Partnership Program (ACHRU-CPP)

Fund Total: $264,599.74

Janssen Pharmaceuticals, December, 2018 – January 2020

Project Title: JPEI-HIP (Janssen – PEI) Health Intelligence Partnership

Fund Total: $150,000

Veteran and Family Well Being Fund, July 1, 2019 – June 30, 2020

Project Title: Trauma-Informed Psychological Treatment and Adjunct Therapies for Veterans and Their Families

Fund Total: $350 000. Funding provided for Renovations, Program Development and Research

Sir James Dunn Animal Welfare Centre, July 1, 2018 – June 30, 2020

Project Title: Recognition of Stress Levels in Hospitalized Equine Patients During Various Veterinary Procedures: Adaptation of a Stabled Horse Stress Scale to a Cohort of Hospitalized Horses

Fund Total: $65,308.00

Total Related Support: $829,907.74

VIII. LAY LANGUAGE ABSTRACT

Background: Post-traumatic stress disorder is a serious mental health problem that is triggered by seeing or living through a terrifying event. Although PTSD can happen to anyone, many military veterans return from war with symptoms that significantly impact their lives. Veterans with PTSD are limited in their options for overcoming symptoms and are increasingly turning to non-traditional treatment methods. Animals, such as horses, provide an important companionship that can help veterans recover; however, the effectiveness and impact of this relationship on both veterans and horses has not been well established.

Plan: Building on previous research, this study will explore the impact of an 8-week therapy program that uses horses to alleviate stress in veterans diagnosed with PTSD. Researchers will collect data from humans and horses that measure stress using both physical (i.e. cortisol, oxytocin, heart rate data, and standardized assessment) and standardized psychological tests. Together these measures will enable the researchers to better understand how the horse assisted

therapy program influences the recovery of veterans diagnosed with PTSD and related mental health symptoms (i.e. anxiety and depression). Sixteen veterans recruited through Veterans Affairs Canada will receive 8-weeks of therapy (once per week) consisting of grooming and leading a horse under the direction of a registered psychologist. Self-reported information about PTSD symptoms, anxiety, and depression will be assessed at the start of the program, after week 4 of the program, at the end of the program, and two months following the program. Saliva and blood samples will be taken from veterans and horses during each session. Data analysis will compare data collected at each point in the therapy program. This study will be unique in that data will be collected from humans and horses at the same time to better understand the human-horse relationship during therapy.

Team: Our team members provide rich and diverse expertise to this project. Project leads include senior faculty members with extensive experience in veterinary medicine and human health, respectively. Collaborators include a registered psychologist with expertise in the clinical treatment of trauma, and PTSD; a clinician with expertise in veterans with PTSD; and a researcher who specializes in microbiology and biotechnology.

IX. BIOGRAPHICAL SKETCH OF PRINCIPAL INVESTIGATOR

NAME: Laurie A McDuffee, DVM, PhD. DACVS

POSITION TITLE: Professor of Large Animal Surgery, Atlantic Veterinary College, University of Prince Edward Island

EDUCATION:

1998	PhD, Comparative Pathology, University of California, Davis, CA
1991-1994	Residency in Equine Surgery, Veterinary Medical Teaching Hospital, School of Veterinary Medicine, University of California, Davis, CA
1990-1991	Internship in Large Animal Surgery, New York State College of Veterinary Medicine, Cornell University, Ithaca, NY
1986-1990	D.V.M., Colorado State University, Fort Collins, CO
1980-1985	B.A., University of Colorado, Boulder, CO

SPECIALTY BOARD CERTIFICATION:

1996	American College of Veterinary Surgeons

SELECTED PUBLICATIONS, ABSTRACTS and PRESENTATIONS (last 3 years):

(* indicates student)

1. **McDuffee L,** Mills M, McNiven M, Montelapre W. Establishing Statistical Stability for Heart Rate Variability in Horses. Journal Vet Behavior. Available online 23 May 2019.
2. *Hamza A, Overall K, Montelpare W, Cockram M, **McDuffee L.** Recognition of Stress Levels in Hospitalized Equine Patients During Various Veterinary Procedures: Adaptation of a Stabled Horse Stress Scale to a Cohort of Hospitalized Horses. Proceedings, 12th International Veterinary Behavior Meeting, Washington DC, August, 2019.

3. *Larissa Carr, **Laurie McDuffee**, William Montelpare. Evaluation of stress in horses during therapeutic riding sessions. Proceedings, Science Atlantic Aquaculture and Fisheries Conference, Moncton, NB, 2019.
4. **McDuffee L,** *Mills M, McNiven M, Montelpare W. Equine Heart Rate Variability Measures: Are they stable from day to day and during different activities? Proceedings, International Society for Applied Ethology, Charlottetown, PEI, 2018.
5. *Molly Mills, **Laurie A. McDuffee**, Mary A. McNiven, William J. Montelpare. Day to day variation in a sample of equine heart rate variability estimates. Proceedings, Boehringer Ingleheim Veterinary Scholars Symposium, Bethesda, MD, 2017 p. 223.
6. *Jane Northrup**, Laurie McDuffee**. A Comparison of the Effectiveness of Positive and Negative Reinforcement for Behaviour Modification of Horses with Aversion to Administration of Oral Medications. Proceedings, Science Atlantic Aquaculture and Fisheries Conference, Antigonish, NS, 2017.

NAME: William J. Montelpare, PhD (CO-INVESTIGATOR)

POSITION TITLE: Professor and Margaret and Wallace McCain Chair in Human Development and Health, University of Prince Edward Island

EDUCATION:

1980	Honours Bachelor of Physical Health Education, School of Physical and Health Education, Lakehead University
1984	M.Sc., Exercise Physiology – Renal Physiology, University of Ottawa, Department of Kinanthropology

1990 Ph.D., Community Health (Biostatistics, Epidemiology, Exercise Science), University of Toronto, Department of Community Health, School of Preventive Medicine and Biostatistics, Faculty of Medicine

SELECTED PUBLICATIONS, ABSTRACTS and PRESENTATIONS (last 3 years):

1. McDuffee L, Nino-Fong R, Esparza Gonzalez B, Rodriguez-Lecompte JC, & **Montelpare W.J.** Development of a Biologically Immortalized Equine Stem Cell Line. Poster Presentation at the Veterinary Orthopedic Research Society Conference and AGM, Aspen, March 2018.

2. McDuffee, LA, Mills, M., McNiven, M., Montelpare, WJ. Establishing Statistical Stability for Heart Rate Variability in Horses. Journal of Veterinary Behaviour, Accepted April 2019. *IN PRESS.*

3. Thompson JM, Dursun S, VanTil L, Heber A, Kitchen P, de Boer C, Black T, **Montelpare W.J.,** Coady T, Sweet J, Pedlar D. Group identity, difficult adjustment to civilian life and suicidal ideation in Canadian Armed Forces Veterans: Life after Service Studies 2016. J Mil Veteran Fam Health. *In Press*.

4. Afifi M, Kabera F, Stryhn H, Roy J-P, Heider L, Godden S, **Montelpare W.J**., Sanchez J, Dufour S. Antimicrobial-based dry cow therapy approaches for cure and prevention of intra-mammary infections: a protocol for a systematic review and meta-analysis. *Animal Health Research Reviews*, 2018;1–5.

5. MacDougal, A., Weeks, L., **Montelpare, WJ.,** Compton, S., The intersection of oral health knowledge and oral health literacy of baby boomers? *Can J Dent Hyg* 2018;52(2): 99-109.

6. Faught, BE., Schachtschneider, C., Law, M., Liu, J., MacLeod, F., Montelpare, WJ., Klassen, K., Does the Pre-employment Screening Process influence Health Status of Probationary Firefighters? *Medical Research Archives*, 2017, 5(9): 1-13.

7. Charlton, P., Azar, R., Luke, A., Doucet, S., **Montelpare, WJ.,** Nagel, DA., Hyndman, N., & Thompson, K. Falling through the cracks: barriers to accessing services for children with complex health conditions and their families in New Brunswick. *Journal of New Brunswick Studies*. 2017, 8, 133-158. https://journals.lib.unb.ca/index.php/JNBS/article/view/25883/30037.

8. Doucet, S, Nagel, DA, Azar, R, **Montelpare, W.J.**, Charlton P, Hyndman N, Luke A, and Stoddard R., A Mixed-Methods Quick Strike Research Protocol to Learn About Children with Complex Health Conditions and Their Families. Int. J. Qual. Methods. 2017, 16:1-12.

9. Reed-Jones R., Carvalho L., Sanderson C., **Montelpare W.J**., Murray N., and Powell D. Examining changes to centre of pressure during the first trials of Wii game play. Games for Health Journal. February 2017, 6(1): 61-64.

10. **Montelpare, W.J**., McPherson, M.N., Boardman, K., Zerpa, C.E., Evaluating The Wizards Of Motion Cardiovascular Disease Prevention Module. *Journal of School Nursing, Journal of School Nursing, Published* May 2017 - DOI: https://doi.org/10.1177/1059840517709074.

11. Ukuhor, H., Hirst, J., Closs, S.J., **Montelpare, W.,** A framework for describing the influence of service organisation and delivery on participation in foetal anomaly screening in England. Journal of Pregnancy, (2017), Article ID 4975091, 13 pages. https://doi.org/10.1155/2017/4975091.

12. Beck, K., MacDonald, D., Weeks, L., **Montelpare, W.,** Identifying important factors for older adults' physical activity participation across individual/group, structured/unstructured contexts. *European Journal of Ageing* 2016, 13:209-218.

NAME: Caroline LeBlanc, Registered Psychologist (COLLABORATOR)

POSITION TITLE: Registered Psychology, Serene View Ranch

EDUCATION:

1988 B.A. Psychology, Universite de Moncton

1991 M.A. Clinical Psychology, Universite de Moncton

PROFESSIONAL EXPERIENCE:

1999-Present: Full time Private Practice in Clinical Psychology

1996-1999 Director of Assessment Services, Holland College

1994-1996 Provincial Government EAP Counsellor

1991-1994 Clinical Psychologist, Department Corrections, PEI

NAME: Angela Riveroll, PhD (COLLABORATOR)

POSITION TITLE: Research Associate, Health-Centered Research Clinic University of Prince Edward Island

EDUCATION:

1994 – 1998 BSc. Honours in Microbiology and Immunology, Dalhousie University

1998 - 2006 PhD in Microbiology and Immunology, Dalhousie University

SELECTED PUBLICATIONS, ABSTRACTS and PRESENTATIONS (last 3 years)

1. Riveroll, A., Murray, S., Thompson, K., Robertson, K., Salijevic, A. and Montelpare, W. Precision Health: A Personalized Approach to Active Health

Management Vol (41): 2018 Canadian Medical and Biological Engineering Society, Charlottetown, PEI. https://proceedings.cmbes.ca/index.php/proceedings/article/view/704/698

2. Nino- Esparza, R., Riveroll, A., McDuffee, L., Montelpare, W.J. and Ahmadi, A. Development of a Saliva-Based Cortisol Biosensor Using Smartphone-Based Image Analysis Vol (41): 2018 Canadian Medical and Biological Engineering Society, Charlottetown, PEI. https://proceedings.cmbes.ca/index.php/proceedings/article/view/696/690

NAME: James M. Thompson, M.D. (COLLABORATOR)

POSITION TITLE: Adjunct Associate Professor, Department of Public Health Sciences, Queen's University, Kingston, Ontario, Canada
Research Medical Consultant, Canadian Institute for Military and Veteran Health Research, Kingston, Ontario

EDUCATION:

1986-87	CCFP(EM) Emergency Medicine Residency, Foothills Hospital
1984-86	CCFP Family Medicine Residency, Foothills Hospital
1981-84	MD University of Calgary
1972-76	BSc (Honours Marine Biology) University of Guelph

SELECETED PUBLICATIONS, ABSTRACTS and PRESENTATIONS (last 3 years):

1. **Thompson JM,** Heber A, Davine J, Murray R, McCreary DR. Recognizing posttraumatic stress disorder in primary care. In R. Ricciardelli, S. Bornstein, A. Hall, & N. Carleton (Eds), Handbook of Post-Traumatic Stress: Psychosocial, Cultural and Biological Perspectives. NY, NY: Informa. (In press).

2. Pedlar D and **Thompson J,** Castro C. Military to Civilian Transition Theories and Frameworks. Chapter 3 in: Castro et al. (eds). Military Veteran Reintegration. Elsevier. 2019 (In press).

3. **Thompson JM,** Dursun S, Lee J, Skomorovsky A, Lockhart W, MacLean MB. Self-assessment of need for assistance with transition to civilian Life. Chapter 5 in: Castro et al. (eds). Military Veteran Reintegration. Elsevier. 2019 (In press).

4. **Thompson JM**, Dursun S, VanTil L, Heber A, Kitchen P, de Boer C, Black T, Montelpare B, Coady T, Sweet J, Pedlar D. Group identity, difficult adjustment to civilian life and suicidal ideation in Canadian Armed Forces Veterans: Life After Service Studies. J Mil Vet Fam Res. 2019. https://jmvfh.utpjournals.press/doi/abs/10.3138/jmvfh.2018-0038

5. **Thompson JM**, Heber A, VanTil L, Simkus K, Carrese L, Sareen J, Pedlar D. Life course well-being framework for suicide prevention in Canadian Armed Forces Veterans. J Mil Vet Fam Res. 2019. https://jmvfh.utpjournals.press/doi/abs/10.3138/jmvfh.2018-0020

6. Tweel M, **Thompson JM**, Lockhart W, Ralling A, Keough J, MacLean MB, VanTil L, Sweet J, Poirier A, Roach MB, Murray R, Svenson N. Veterans Affairs Canada Research Directorate Publications: Annotated Bibliography 1997-2018. Charlottetown PE: Research Directorate, Veterans Affairs Canada. Research Directorate Technical Report. 2019. https://cimvhr.ca/vac-reports/data/reports/Tweel%20M%202019%20Research%20Directorate%20Annotated%20Bibliography.pdf.

7. Forbes D and Pedlar D, Adler AB, Bennett C, Bryant R, Busuttil W, Cooper J, Creamer MC, Fear NT, Greenberg N, Heber A, Hinton M, Hopwood M, Jetly R, Lawrence-Wood E, McFarlane A, Metcalf O, O'Donnell M, Phelps A, Richardson JD, Sadler N, Schnurr PP,

Sharp M-L, **Thompson JM**, Ursano RJ, Hooff MV, Wade D, Wessley S. Treatment of military-related posttraumatic stress disorder: Challenges, innovations, and the way forward. International Review of Psychiatry. 2019. DOI: 10.1080/09540261.2019.1595545 https://www.tandfonline.com/doi/full/10.1080/09540261.2019.1595545.

8. Besemann M, Heber J, **Thompson J**, Cooper RA, Gupta G, Brémault-Phillips S, Dentry SJ. Reflections on recovery, rehabilitation and reintegration of injured service members and veterans from a bio-psychosocial-spiritual perspective. Can J Surg. 2018; 61(6 Suppl 1) : S219-S231. DOI: 10.1503/cjs.015318 http://canjsurg.ca/61-6-s219/.

9. Sareen J, Holens P, Turner S, Jetly R, Kennedy S, Heisel M, Cooper K, Mota N, Comtois K, Stein MB, Schaffer A, **Thompson J**, Heber A. Report of the 2016 Mental Health Expert Panel on Suicide Prevention in the Canadian Armed Forces. J Mil Veteran Fam Health. 2018;4(1):70-89.

10. **Thompson JM**, Lockhart W, Roach MB, Atuel H, Bélanger S, Black T, Castro CA, Cox D, Cooper A, de Boer C, Dentry S, Hamner K, Shields D, Truusa, TT. Veterans' Identities and Well-being in Transition to Civilian Life – A Resource for Policy Analysts, Program Designers, Service Providers and Researchers. Report of the Veterans' Identities Research Theme Working Group, Canadian Institute for Military and Veteran Health Research Forum 2016. Charlottetown PE: Research Directorate, Veterans Affairs Canada. Research Directorate Technical Report. 01 June 2017.

11. **Thompson JM**, Dursun S, Lee J, Skomorovsky A, Lockhart W, Macintosh S, MacLean MB. Self-assessment of Need for Assistance with Transition to Civilian Life: Development of the Road to Civilian Life (R2CL) Transition Checklist. Charlottetown, PE: Research Directorate, Veterans Affairs Canada and Ottawa, ON: Director General Military

Personnel Research and Analysis, Canadian Armed Forces. VAC Research Directorate Technical Report. 26 January 2017.

12. **Thompson JM**, Sweet J, VanTil L, Poirier A, MacKinnon K. Correlates of Mental Health Problems in Canadian Armed Forces Veterans – 2013 Life After Service Survey. Charlottetown PE: Research Directorate, Veterans Affairs Canada. Research Directorate Technical Report. Charlottetown. 14 September 2016.
13. **Thompson JM**, Zamorski MA, VanTil L, Fikretoglu D, Dursun S, Sweet J, Garber B, Richardson JD, Sareen J, Courchesne C, Pedlar D. Composite Measure of Mental Health Problems in Canadian Armed Forces Veterans – the 2013 Life After Service Survey. Charlottetown, PE: Veterans Affairs Canada. Research Directorate Technical Report. 2017.

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 University of Prince Edward Island agrees that if a research grant is awarded by the Horses and Humans Research Foundation (HHRF) to Professor Laurie McDuffee, Ph.D., DVM, for the project: Psychophysiological effects of Equine-assisted therapy on horses and in veterans diagnosed with post-traumatic stress disorder (PTSD) 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 Province of Prince Edward Island, the University of Prince Edward Island 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

_____

Signature

_____

Type/Print Name and Title of Dean or Head of Institution

_____

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 University of Prince Edward Island agrees that if a research grant is awarded by the Horses & Humans Research Foundation (HHRF) to Laurie McDuffee for the project: Psychophysiological effects of Equine-assisted therapy on horses and in veterans diagnosed with post-traumatic stress disorder (PTSD), 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 Province of Prince Edward Island, the University of Prince Edward Island 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

_____
Signature

_____
Type/Print Name and Title of Dean or Head of Institution

_____
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. The grant time line will commence of the day that the grant is awarded or the day that evidence of final IRB approval (if still under consideration) is submitted to HHRF (within 3 months of grant award).
3. 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.
4. 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.
5. Grant awards will be made in US dollars. One third of the awarded amount will be paid once the contract is signed by all parties. One third 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).
6. 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. Pictures and additional marketing materials are requested to be submitted during the grant term or with the final report. 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 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.
7. 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.

8. 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. HHRF also has permission to share results of this study through publications and outreach materials.
9. 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.
10. All studies involving equine assisted horses must comply with accepted industry standards for care, treatment, and humane work load. All related program work must comply with accepted industry standards for safety – including a certified instructor/therapist/clinician or evidence of equivalent standards. Therapeutic program sites must be accredited by or provide evidence of equivalent standards for facility safety.
11. A one and a half year grant period is assumed. Projects that do not comply with the approved timelines will be put into probationary measures and funding will be placed in fiscal holding. (When placed on fiscal hold no further funds can be released without a hearing by HHRF board representatives who will review the entire grant history and determine any further actions).
12. 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.
13. 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.
14. 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: _____
Date: _____

Principal Investigator's name and title: Laurie McDuffee Professor, Atlantic Veterinary College, University of Prince Edward Island

I. ATTACHMENTS

A. REFERENCES

Acharya, U.R., Kannathal, N., Lim, C.M. & Suri, J. (2006). Heart rate variability: a review. *Medical and Biological Engineering and Computing, 44*(12), 1031-1051.

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Church, D., Yount, G., Rachlin, K., Fox, L. & Nelms, J. (2018). Epigenetic effects of PTSD remediation in veterans using clinical emotional freedom techniques: a randomized controlled pilot study. *American Journal of Health Promotion, 32*(1), 112-122.

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Shivakumar, G., Anderson, E., Suris, A. & North, C. (2017). Exercise for PTSD in women veterans: a proof-of-concept study. *Military Medicine, 182*, e1809-e1814.

Stevelink, S., Jones, M., Hull, L., Pernet, D., Maccrimmon, S., et al. (2018). Mental health outcomes at the end of the British involvement in the Iraq and Afghanistan conflicts: a cohort study. The British Journal of Psychiatry, 214(3). doi: 10.1192/bjp.2018.235.

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Vella, E.J., Milligan, B. & Bennett, J.L. (2013). Participation in outdoor recreation program predicts improved psychosocial well-being among veterans with post-traumatic stress disorder: a pilot study. *Military Medicine, 178*, 254-260.

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Wharton, T., Whitworth, J., MacAuley, E. & Malone, M. (2019). Pilot testing a manualized equine-facilitated cognitive processing therapy (EF-CPT) intervention for PTSD in veterans. *Psychiatric Rehabilitation Journal*, 1-9. doi: 1095-158X.

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B. Letter of Support

SERENE VIEW RANCH PSYCHOLOGICAL SERVICES
Mailing Address: P.O. Box 24076, Stratford, PE C1B 2V5
Location: 174 Pickles Lane, Alexandra, PE
Telephone: 902-393-3829; Fax: 902-569-8197
Website: www.sereneviewranch.com

To: Dr. Laurie McDuffee

From: Caroline LeBlanc

RE: Research Proposal

Date: July 25, 2019

Dear Dr. McDuffee,

The following is to confirm that Serene View Ranch, Psychological Services, is interested in participating in the research that will be conducted by yourself under the HHRF. The research proposed, titled Psychophysiological effects of Equine Assisted Therapy in Horses and Veterans: Exploring the influence of Post Traumatic Stress Disorder, fits within the area of work that SVR does with Veterans. Research in this area is limited, but interest in the therapeutic benefits of horses is on the rise, as programs are being developed across the world.

Please let us know if there is anything else that we can do. We can be reached at 902-393-3829.

Sincerely,

Caroline LeBlanc
Registered Psychologist

Clinical Team
Derek Anderson, MSW; Tara Costello, M.A., Randell Duguid, MSW; Sandra Fraser, RN;
Barbara Jones, M.A.; Alan Kostyniuk, M.Ed., Caroline, LeBlanc, M.A.; Donna MacLeod, OT;
Danny Miles, M.A.; Nancy Montgomery, M.A.

C. IRB Application (with informed consent form)

ETHICS REVIEW PROTOCOL SUBMISSION FORM

Submit **one original signed copy** of the submission form and all other application documents including the research proposal or grant application, consent form(s), research instruments, and a certificate of completion for the TCPS 2 Tutorial to **Research Services, 200 Kelly Building, UPEI** *and* send **one electronic copy** of all application documents to reb@upei.ca. Researchers are urged to consult the Tri-Council Policy Statement 2 for more information and guidance.

*** Submissions are regarded by the REB as strictly CONFIDENTIAL**

SECTION 1: IDENTIFICATION				
Project Title:	Psychophysiological effects of Equine-assisted Therapy in Horses and in Veterans diagnosed with PTSD			
Principal Investigator:	Laurie McDuffee, Professor Large Animal Surgery			
Department/Faculty:	Atlantic Veterinary College			
Phone:	902-566-0996		**UPEI ID:**	79890
Email:	lmcduffee@upei.ca			
***STUDENT submissions: provide the following information and attach the Confirmation of a Supervisor's Review Form.**				
Supervisors Name:	Click here to enter text.			
Degree Program:	Click here to enter text.		**Department:**	Click here to enter text.
Project Period:	From (MM/DD/YY)	01/01/2020	To (MM/DD/YY)	30/06/2021
Is this project funded?	Yes ☒ No ☐		Funding Agency:	HHRF: Human and Horse Research Foundation
Have you signed a Release of Funds Agreement? Yes ☐ No ☒				
If unfunded, name two possible reviewers:				
1.		2.		
Does your project involve the use of animals Yes ☒ No ☐				
Does your project involve biohazards? Yes ☐ No ☒				
Does this study qualify as involving **MORE THAN MINIMAL RISK**?				

Yes ☐ No ☒			
Has this project been reviewed or approved by any other Research Ethics Board? Yes ☐ No ☒			
If yes, provide the name/s of the other REB and date/s of approval:	Click here to enter text.		
Signature of Local PI attesting that: **a.** I agree to abide by the ethical guidelines and procedures of the University of Prince Edward Island Research Ethics Board (UPEI Research Ethics Policy, current version), of the Tri-Council Policy Statement (current version), of my profession or discipline, as well as of the institution in which the research is undertaken. I am aware of my responsibility to be familiar with these standards**.** **b.** I further agree to notify the UPEI REB of any change in the methodology or status of the research project and to comply with requests made by the REB during the life of this research.			
Signature:		**Date:**	

Project Personnel (including students)			
Name:	William Montelpare	**Name:**	Carolyn Leblanc
Role:	Human health measures	**Role:**	Registered Psychologist – Director of Serene View Ranch – Administer Program
Email:	wmontelpare@upei.ca	**Email:**	caroline11leblanc@gmail.com
Name:	Angela Riveroll	**Name:**	Jim Thompson
Role:	Human Laboratory Investigations	**Role:**	Research Collaborator
Email:	ariveroll@upei.ca	**Email:**	jimmt@me.com
Name:			
Role:			
Email:			

SECTION 2: PROJECT INFORMATION

2.1 SUMMARY

2.1.1 Briefly describe the rationale and purpose of the study.

The proposed study aims to build on previous research examining the impact of EAA/T on PTSD symptoms in veterans and fill the observed gap on animal welfare. In order for equine assisted therapy (EAT) to be a useful long-term treatment for veterans, science needs to provide evidence that the therapy is beneficial to humans and is not adverse to the horses. The current study aims to obtain objective physiological and psychological data from veterans and horses that engage in EAA/T. Effect of therapy on humans and horses will be determined through cortisol as an indicator of stress, oxytocin as an indicator of stress modulation, the balance between the sympathetic and parasympathetic branches of the autonomic nervous system (e.g. through HRV); and by standardized assessment (humans) and behavioral indicators (horses) of stress. The proposed analysis is novel in the representation of paired data from the human-horse dyad.

Specifically, the purpose of the study is to evaluate psychophysiological effects of Equine-Assisted Activities and Therapy (EAA/T) in Horses and in Military Veterans diagnosed with PTSD

2.1.2 What new knowledge is anticipated as an outcome of the study?

This study will be innovative in its approach to studying the potential effects of EAA/T through a unique approach to data collection and analysis. Specifically, similar mixed methods data will be obtained from both human participants (i.e. veterans) and horses simultaneously to gain insight into the psychophysiological aspect of the human-horse dyad during therapy.

Few investigations have explored the process of entrainment between humans and their horses, which posits that the physiological processes (e.g. HRV, etc) of humans and horses become rhythmically "in sync" with one another. The current study will examine this theory further and assess whether it contributes to any observed changes as a result of EAA/T in both the human participants (i.e. veterans) and horses.

Pilot work in the proposed area of study are ongoing. Recent publications and presentations by our research team include the determination of statistical reliability of heart rate variability in a sample of horses performing normal daily activities (walking, in cross-ties, and standing in a box stall) (Mills et al, 2017), (McDuffee, et al, 2019); evidence of stress during EAA/T among a sample of therapeutic riding horses in a CANTRA registered program (Carr, et al, 2019), and to determine stress among horses introduced to a teaching hospital (Hamza, et al, 2019). In these research studies our objective has been to establish the methodologies for scoring behaviours, assessing stress via salivary cortisol concentrations, and establishing the appropriate regimen for collecting and analyzing heart rate variability measures.

2.2 STUDY DESIGN

2.2.1 State the Hypothesis or Aim (or research question or research objectives).

Using a prospective cohort research design this study intends to study the effects of EAA/T on horses and the influence of EAA/T on military veterans diagnosed with PTSD. In addition, the study will explore the presence of entrainment between humans and horses as reflected in selected physiological measures. The sample will be comprised of 16 individuals, each matched with a therapy horse for the intervention period. In this design, the independent variable EAA/T, defined as one-hour therapeutic sessions consisting of grooming and leading the horse in a heated arena. The dependent variables involve four standardized psychological assessments measuring anxiety, depression, anger, and PTSD symptoms; and physiological measures in humans and horses, as measured by salivary cortisol, oxytocin, and HRV. Covariables will include, but not limited to existing pharmacological regimens, sex of the human and horse, veterans' years of service, and age.

We hypothesize that humans will have a decrease in PTSD symptoms that will include a decrease in anxiety, anger and depression as measured by standardized psychological instruments, and corroborated through laboratory estimates of cortisol, oxytocin, and ANS responses determined by HRV. We further hypothesize that horses involved in EAA/T will be influenced to a measurable extent as a function of their participation.

- **Hypothesis 1**: Veterans will demonstrate a decrease in cortisol levels post intervention as compared to baseline testing
- **Hypothesis 2:** Veterans will demonstrate an increase in oxytocin levels post intervention as compared to baseline testing
- **Hypothesis 3**: Veterans will report an improvement in standardized psychological

assessments of anxiety, depression, and anger

- **Hypothesis 4**: Levels of cortisol and oxytocin in horses participating in EAA/T will change post intervention as compared to baseline testing
- **Hypothesis 5:** Horses will demonstrate a decrease in observable stress behaviors as a function of their participation in EAA/T

Hypothesis 6: Objectively collected data will demonstrate a synchronization between humans and horses

2.2.2 Provide the justification for the study. Address scholarly/scientific validity of the study and the appropriateness of utilizing human participants.

Post-traumatic stress disorder (PTSD) is a psychiatric disorder that occurs in persons after experiencing or witnessing a traumatic event (APA, 2017). The condition is characterized by intrusive thoughts, avoidance, negative thoughts and feelings, and over arousal (APA, 2013), and is associated with numerous comorbidities (Krondish et al., 2012; Park et al., 2017) including depression (Bersani et al., 2016); anxiety (Church et al., 2018); chronic pain (Otis et al., 2013); hypertension (Moazen-Zadeg et al., 2016); and substance abuse-related issues (Johnson et al., 2016). PTSD can be a chronic and disabling condition, affecting all areas of a person's well-being (Bhatnager et al., 2013). Although observed across the general population (Kilpatrick et al., 2013), PTSD is particularly prevalent in military veterans who have been exposed to combat duties (Hines et al., 2014; Stevelink et al., 2018).

Veterans with PTSD often struggle with emotion and impulse control resulting in the inability to appropriately handle even minimal stress and leading to physiological dysregulation (Jerg-Bretzke et al., 2013; Mozaen-Zadeh et al., 2016). PTSD is marked by increased sympathetic activation and decreased parasympathetic responses in the autonomic nervous system (ANS), which can cause disruptions in heart rate variability (HRV) (Cohen et al., 2000). HRV is an objective physiological parameter used to assess and monitor variation in heartbEAA/T intervals (Acharya et al., 2006) and is a noninvasive method of assessing the autonomic systems (Bhatnager et al., 2013). Studies investigating HRV in veterans with PTSD have shown that individuals often demonstrate lower HRV than the general population (Park et al., 2017). Low HRV is indicative of an ANS system in state of perpetual fight-or-flight mode, which is associated with many mental and physical conditions (Campos, 2017). Changes in HRV have been noted to correlate with changes in PTSD symptoms, as measured by the Clinical Administered PTSD Scale (CAPS), suggesting that HRV may be a biomarker of disease and treatment response (Bhatnager et al., 2013).

PTSD has been associated with medication non-adherence (Wasson et al., 2018), which is posited to increase mortality rates in patients living with the diagnosis (Krondish et al., 2012). Moreover, previous investigations into the use of medication for treatment of PTSD has shown that medical intervention alone may not be sufficient (Mann & George, 2017). This observed limitation to clinical treatments has led to numerous attempts to evaluate alternative, non-medical interventions such as animal assisted therapy (AAT).

Animal assisted therapy (AAT) in veterans with PTSD

Animal assisted therapy (AAT) is used to promote the mental and physical health of humans (O'Haire, Guerin & Kirkham, 2015). Previous studies using animal assisted therapies for veterans with PTSD have demonstrated positive effects on symptoms of PTSD (Wortman et al., 2018) and comorbidities, such as anxiety and depression (O'Haire, Guerin & Kirkham, 2015; van Houtert et al., 2018). One particular field of interest is the use of equine assisted activities and

therapies (EAA/T) for treatment of PTSD in military veterans. Horses provide a unique therapeutic experience for veterans diagnosed with PTSD due to their large size and nature as a prey animal. The interaction between veterans and horses can help participants improve communication skills and confidence in a way that appeals to the veteran's sense of adventure and achievement (Masini, 2010; Latella & Abrams, 2015).

Veterans report seeking participation in equine-assisted activities due to feelings of helplessness and hopelessness, as well as a desire to seek social connections (Lanning & Krenek, 2013). Horses communicate primarily through body language (Lentini & Knox, 2009) and respond to humans' emotions and behaviors (Burgon, 2011; Karol, 2007; Latella & Abrams, 2015). It is believed that these qualities of the horse facilitate the therapeutic effect by allowing humans to identify with the horses' natural instinct to seek safety and security (Latella & Abrams, 2015; Masini, 2010). Veterans with PTSD interact with horses through mounted and unmounted activities to work through concerns in a natural and physically challenging environment (Latella & Abrams, 2015).

Equine assisted interventions are characterized by a unique environment outside of the typical office setting. Previous investigations on non-medical interventions have shown that veterans with PTSD may benefit from participation from outdoor recreational activities through increases in well-being and decreases in symptoms of PTSD (Bhatnagar et al., 2013; Church et al., 2018; Jasbi et al., 2018; Vella, Milligan & Bennett,, 2013). Physical exercise (Shivakumar et al., 2017; Whitworth & Ciccolo, 2016) and leisure functioning (Johnson et al., 2016) are also believed to contribute to the success of EAA/T in reducing symptoms of PTSD.

EAA/T has been increasingly observed as a valuable intervention in the mental health field in recent decades (Brandt, 2013). A wide variety of programs have been developed in the United States and Canada, incorporating horses on the ground and with riders. The Mindful Warriors Equine Therapy Program, for example, is an eight-week intervention that incorporates horseback riding and psychotherapy to help veterans regulate their physiological responses to stress and other emotional states, as well as to recognize their relationship patterns and deepen connections with others through the relationship with the horse.

Evaluation of EAA/T in veterans with PTSD

Empirical evidence on the use of horses to treat PTSD symptoms in veterans is conflicting, perhaps owing to a low level of methodological standardization and rigor across studies (O'Haire, Guerin & Kirkham, 2015). Use of horses for treatment of PTSD has been shown to be effective at decreasing the impact of symptoms (Malinowski et al., 2018) through activities such as grooming, leading, and riding the horse with the goal of improving muscle function and coordination; increasing communication skills; and decreasing stress (Lanning & Krenek, 2013). Similarly, Wharton and colleagues (2019) evaluated the impact of EAA/T through an activity designed to assist veterans in overcoming behaviors that play a role in combat-related trauma (e.g. force versus coercion). The EAA of interest involved leading a horse without a rope or physical contact. Investigators observed significant improvements from baseline on standardized assessments related to symptoms of PTSD and good working relationships, as determined by the Working Alliance Inventory (WAI) and Human Animal Bond Scale (HABS).

Despite these observed positive effects of EAA/T, some studies were not able to replicate findings. Burton and colleagues (2019), for example, did not find a significant impact of equine assisted psychotherapy in symptoms of PTSD. Symptoms in veterans receiving EAA/T were compared to a control group that received standard therapy for the treatment of PTSD. Both groups

demonstrated an improvement in PTSD symptoms and decrease in cortisol levels, however, did not significantly differ from one another. These results suggest that although EAA/T was not superior to standard treatment, the use of horses for therapy provided similar results to standard PTSD therapy. The American Psychological Association (APA) recognizes two types of standard treatment for PTSD, including psychotherapy and pharmacotherapy (APA, 2017). Although EAA/T is not currently recognized by the APA as an evidence-based psychotherapy for PTSD treatment (APA, 2017) these findings suggest that use of therapy horses may be an alternative method of PTSD treatment that yields similar results. There is an expressed need for evaluation methods beyond self-perceived welfare of assisted humans in order to move towards a standardization in scientific methodologies using objective measurement techniques (van Houtert et al., 2018).

Impact of EAA/T on horses

Although much research has been conducted on the assessment of AAT on humans, little is known about the effect of these interventions on the animals (O'Haire, Guerin & Kirkham, 2015). The lack of developmental standardization regarding the potential impact of the therapy on animal welfare poses potential risks to both animals and humans (van Houtert et al., 2018). In a systematic review on EAA, O'Haire and colleagues (2015) noted that no outcomes related to animal welfare were reported in identified primary studies. Investigators argue that animal welfare is crucial to successful and ethical outcomes from human-animal interactions.

This need for a focus on animal welfare in EAA/T is further emphasized in the Five Domain Model (Mellor, 2017). This framework describes five critical areas relevant to animal welfare assessment and management, including: nutrition; environment; health; behaviour; and mental state. Mental state of horses is a particularly important consideration in EAA/T for veterans with PTSD. Entrainment theory describes a process of mirroring in the interaction between independent mechanisms (Clayton, 2012), such as between the physiology of the horse and human during EAA/T. In other words, entrainment suggests that the functioning of a human's psychophysiology may have an affect on the health of the animal. This has led to concerns for the welfare of horses in AAT when the human participate has poor mental health, such as veterans with PTSD symptoms. Studies focusing on the potential impact of EAA/T on equine welfare has shown mixed findings; stress levels in horses, as measured by plasma cortisol concentrations and heart rate, have been shown to increase in some studies (Keeling, Jonare & Lanneborn, 2009) while remaining unchanged in others (Malinowski et al., 2018). Further research on the impact of EAA/T on animal welfare is needed to develop therapeutic understandings of the potential success of EAA/T (Wortman et al., 2018). Moreover, the available evidence on the use of AAT in persons that have experienced trauma, such as PTSD, suggests that it is a promising treatment option, however more research is needed (O'Haire, Guerin & Kirkham, 2015).

2.2.3 Describe the plan for data analysis in relation to the hypotheses/questions/objectives.

The proposed study aims to build on previous research examining the impact of EAA/T on PTSD symptoms in veterans and fill the observed gap on animal welfare. In order for equine assisted therapy (EAP) to be a useful long-term treatment for veterans, science needs to provide evidence that the therapy is beneficial to humans and is not adverse to the horses. The current study aims to obtain objective physiological and psychological data from veterans and horses that engage in EAA/T. Effect of therapy on humans and horses will be determined through cortisol as an indicator of stress, oxytocin as an indicator of stress modulation, the balance between the sympathetic and parasympathetic branches of the autonomic nervous system (e.g. through HRV);

and by standardized assessment (humans) and behavioral indicators (horses) of stress. The proposed analysis is novel in the representation of paired data from the human-horse dyad and can be separated as follows:

i) Horses: Boris software will be used to evaluate stress behaviors observed during the sessions.
ii) In both human and horse participant the Kubios software for heart rate variability will be used to evaluate time and frequency domain measures that demonstrate autonomic nervous system responses. In saliva and blood sample drawn from the horse participants ELISA techniques will be used to assess concentrations of cortisol, while assessment of measures of Oxytocin will be evaluated by Salimetrics Laboratories.
iii) Psychological surveys will be applied to Military Veterans
iv) All data will be analyzed using SAS to evaluate physical and psychological measures such as plasma cortisol and oxytocin concentrations, as well as HRV estimates (time-domain – meanHR, meanRR, SDNN; frequency-domain – LF/HF ratio) in both the horses and humans, and all pre- and post-survey measures.

2.2.4 Is this intended to be a pilot study, or fully developed project?
This is a pilot study. If the research proves to be successful then this study will be extended to other cohorts.

2.2.5 If a phased review is being requested, describe why it is needed and which phases are contained in this application.
NA

2.3 DETAILED METHODOLOGY

2.3.1 Where will the research be conducted?
The research will be conducted at Serene View Ranch in the village of Pownal, Province of Prince Edward Island, Canada.

2.3.2 What will the participants be asked to do? How long will it take to complete each task? Provide the total time required by each participant to complete all tasks.
Potential research participants will be asked to take part in a 20- 30 minute information session during which the research objectives and protocol will be described prior to seeking consent.

Measurement of symptoms of PTSD in veterans will be collected at three predesignated time points using four standardized surveys: the Multidimensional Anxiety Questionnaire (MAQ), the Beck Depression Inventory (BDI-II), and the **STAXI-2** State **Anger scale** which assesses the intensity of **anger** as an emotional state at a particular time, and the PTSD Checklist (PCL-5) which is a 20-item self-administered assessment designed to measure symptoms of PSTD . The schedule for data collection will be prior to the first EAA/T session on day 1, after four sessions of EAA/T, and at the end of 8 sessions of EAA/T.

In addition, veterans will complete a self-perceived well-being scale consisting of a 10 item scale ranging from unwell to well with verbal anchors at the start and end of each EAA/T session to evaluate state changes in mood.

Objective measurements of HRV, cortisol and oxytocin will be collected from human subjects using Polar Heart Rate Monitors and from passive drool samples, respectively.
HRV data will be collected 30 minutes prior to each session during a resting period (baseline) and throughout each session. Specifically, heart rate monitor recording will be started when the monitors are placed on each individual 30 minutes before the therapy sessions begin, continued during the entire 1 hour EAAT session, and for an additional 30 minutes after EAAT, for a total of 2 hours. For each person, 10 minutes of HRV data before each session, 10 minutes during

grooming of horses, 10 minutes at the midpoint of the time spent with the horses, 10 minutes during leading, and 10 minutes after the session will be collected for a total of five time periods of HRV for analysis. Passive drool will be collected 30 minutes prior to each session during a resting period (baseline) and at the end of each session. Passive drool will be submitted to Salimetrics, LLC for cortisol and oxytocin analysis.

Horses will be instrumented with Polar Heart Rate monitors and will have saliva and blood samples collected for HRV, salivary cortisol and plasma oxytocin measures, respectively. Heart rate monitor recording will be started when the monitors are placed on each horse 30 minutes before the therapy sessions begin, continued during the entire 1 hour EAAT session, and for an additional 30 minutes after EAAT, for a total of 2 hours. For each horse, 10 minutes of HRV data before each session, 10 minutes during grooming, 10 minutes at the midpoint of the time spent with the veterans, 10 minutes while being led, and 10 minutes after the session will be collected for a total of five time periods of HRV for analysis.

Equine blood samples (10 mL) will be obtained via jugular venipuncture at rest, 30 minutes before the start of each session, and at the conclusion of the EAA/T session to measure plasma oxytocin. Equine saliva samples will be obtained with steri-swabs inserted into the corner of the horse's mouth at rest, 30 minutes before the start of each session, and at the conclusion of the EAA/T session to measure cortisol. To account for the diurnal rhythm fluctuations of cortisol, samples will be taken at approximately the same time each day (from 1300 to 1500 hours). Positive reinforcement will be used during collection of blood and saliva so that horses do not become averse to the collection of samples. Plasma oxytocin will be determined using an Enzyme Immunoassay from Enzo Life Sciences, Inc. Salivary cortisol concentrations will be determined using an ELISA kit from Salimetrics previously validated for use in horses.

In addition, horses will be video recorded for 30 minutes before each session at rest (baseline) and during each session. Recordings will be evaluated for stress behaviors using Behavioral Observation Research Interactive Software (BORIS).

HRV data from humans and horses will be analyzed using Kubios software to determine HRV time and frequency domain measures.

2.3.3 Describe what data will be recorded and what research instruments will be used (attach copies).

This study is designed to measure and assess acute physiological changes in markers of stress and well-being in horses and humans as a result of participation in 8 EAA/T sessions with a registered psychologist and certified equine specialist. The study will be conducted at UPEI in partnership with Serene View Ranch. The EAA/T will take place at Serene View Ranch which is accredited as a premier facility by the EAGALA. Four humans and four horses will participate in the research project during each of 4 eight-week sessions. Humans and horses will data collected before and after each session during the 8 weeks of therapy.

A registered psychologist will oversee the EAA/T. Research personnel from the University of Prince Edward Island (Departments of Human Science and Atlantic Veterinary College) will collect data from humans and horses during the course of the therapy.

2.3.4 Describe the roles of the study investigators and research staff.

Dr. Laurie A. McDuffee, DVM, PhD, DACVS – the primary investigator responsible for the entire project and knowledge translation to healthcare providers and policy makers. will be

responsible for overall study implementation and coordination, and will lead the equine aspect of the research
Dr. William Montelpare PhD – a Professor and Research Chair will be a co-investigaotr with Dr. McDuffee on this project
Dr. Angela Riveroll, PhD – a Research Associate responsible for the oversight on the application of human biological measures.
Dr. Jim Thompson, MD will be a co-investigator assisting in the research design and application of measures.
Caroline Leblanc, Registered Psychologist, will lead the Equine-assisted Therapy. Caroline completed training in EMDR in 2013, Sensorimotor Psychotherapy and has been certified in Equine-assisted Psychotherapy, both with EAGALA and Natural Lifemanship.

2.3.5 For research involving sensitive issues (e.g. abuse) what ethical qualifications do the research team members have?
Dr. Jim Thompson, MD is a former Veterans Affairs Canada researcher Caroline Leblanc, is a Registered Psychologist

2.4 RECRUITMENT / PARTICIPANTS

2.4.1 Total no. of Participants 16

2.4.2 Sources of Participants Veterans Affairs Canada provide clients that are attending the Serene View Ranch

2.4.3 Describe the method of recruiting participants including who will contact them. Provide a copy of the advertisement and/or recruitment notice/script to be used. Indicate when participants will be approached. Describe the participant inclusion and exclusion criteria.
Participants will be recruited through the Serene View program by advertisement and program notices. A 20-minute information session will be presented to the Veterans, describing the study.
Inclusion criteria: Veterans diagnosed with PTSD

2.4.4 Are vulnerable participants being recruited? (e.g., inmates, patients, etc.) Yes ☒ No ☐

2.4.5 If yes who? (specify groups)
Patients who have been diagnosed with PTSD will be recruited to this study.

2.5 RISK AND BENEFITS (only if more than minimal risk)

2.5.1 If more than minimal risk is involved then discuss the risks of the proposed research to all parties, specifying the particular risks associated with each procedure, test, interview, or other aspect of the protocols.
Click here to enter text.

2.5.2 Describe the estimated probability of these risks (e.g., low, medium, high or more precisely if possible).
Click here to enter text.

2.5.3 Describe what steps will be taken to mitigate the risks.
Click here to enter text.

2.5.4 Describe what risks might exist for communities that are involved in the study.
Click here to enter text.

2.5.5 Describe the direct benefits (if any) of participation to participants (not compensation).
Click here to enter text.

2.6 INFORMED CONSENT PROCESS

2.6.1 Describe the informed consent process (attach a copy of all consent forms). Potential participants will be introduced to the study through a 20 minute presentation in which the purpose and expectations of the study will be described. Letters of informed consent will be provided to the potential participants if they so choose to participate, and collected by members of the research group following the presentation by the research group.
2.6.2 If oral consent is desired, describe why it is necessary and how it will be done (attach a copy of the script). n/A
2.6.3 If a waiver of informed consent is sought, please justify. N/A
2.6.4 For third party consent (with or without assent), describe how this will be done. N/A
2.6.5 Describe the need for, and the plans (if any) for on-going consent. Click here to enter text. N/A
2.6.6 If community consent is needed, describe how it will be obtained. N/A
2.6.7 What effort has been made to recruit an inclusive sample? The project is based on the principles of the PEI SPOR PIHcI Network in which an advisory board comprised of patients, community stakeholders, and researchers will ensure that a representative sample of the cohort is included in this research study.
2.6.8 Are the participants competent to consent? Yes ☒ No ☐
2.6.9 If no, who will consent? In the case of severe brain injury participants, consent will be sought from the next of kin.
2.6.10 Are children involved? Yes ☐ No ☒
If yes, what age groups? ☐ Newborn (0-6 months) ☐Pre-school age (6m to 4y) ☐ High School (16-18y) ☐ Primary School (5-11 years) ☐Middle School (12-15 y)
How will the children be recruited? ☐ Through school ☐ Through another institution* (Specify) ☐ Through parents/family ☐Other (Specify) ***** A letter to the institution asking for permission to conduct the study MUST be attached.***
Will the parent's/guardian's consent for the child to participate be obtained? Yes ☐ No ☐
If yes, will the child's assent to participate be obtained? Yes ☐ No ☐
If no, please explain: Click here to enter text.
If students are being recruited, are they the researchers own students? Yes ☐ No ☐
2.7 DECEPTION / INCOMPLETE DISCLOSURE (if applicable)

2.7.1 Describe what misdirection will be used (if any) and discuss its justification. N/A
2.7.2 Describe what relevant information will not be disclosed to participants and discuss its justification. N/A
2.7.3 Describe how participants will be debriefed and given the opportunity to withdraw their data. It will be clearly stated on the consent form that participants can exit the study at any point with no penalty. Participants will be advised when biological samples and data are destroyed or deleted.
2.8 CONFIDENTIALITY AND ANONYMITY
2.8.1 Are the data being collected of a personal or sensitive nature? Yes ☐ No ☒
2.8.2 Describe how the data will be collected, stored and handled in a confidential manner. Who will have access to the data? Data will be stored in a locked filing cabinet in Rm 111, Steel Building where staff of the PEI SPOR PIHcI Network have access. This data will be handled on a laptop that has no wireless capabilities. De-identified data will transfered to our SAS Studio Suite on the UPEI computer servers for analysis.
2.8.3 How long will the data will be retained? What are the plans for their disposal? The data will be retained indefinitely in the secured location as described above.
2.8.4 Is it possible for participants to remain anonymous? If yes, how will this be achieved? No
2.8.5 Will a waiver of confidentiality be sought from participants? If so, why? No
2.8.6 How will de-identification be handled in publication of results to minimize the risk of a breech of anonymity? Data will be coded, no identifiers will be presented, and recruitment location will be withheld.
2.8.7 How will confidentiality be maintained in focus groups (if applicable)? Educational presentations may be done in a group setting, but the consenting process will be conducted one on one.
2.9 COMPENSATION AND DEBRIEFING
2.9 1 Describe what compensation will be offered to participants (if any), how it will be provided, and how it will be handled for participants who do not complete the study. N/A

2.9.3 Amount of compensation	N/A

2.9.4 Describe your plans for adequate and timely debriefing. Attach a script of the basic debriefing given to participants at the completion of their participation. Research findings will be summarized and presented to the participants at an information session, in an effort to build a community for citizen science. Briefly, the content will include a general thank you for participation, followed by presentation of the summarized data. For those who cannot attend, a brochure will be prepared that summarizes the finding in lay language.
2.9.5 Describe your plans for informing participants of the results of the study

Please see above
2.10 CONFLICT OF INTEREST
2.10.1 What direct or indirect benefits (if any) are you, as PI, receiving as a result of this research? None
2.10.2 Do you or your collaborators have any affiliation with, or financial involvement in, any organization or entity with a direct or indirect interest in the subject matter or materials of this research? If yes, provide details. There are no conflicts of interest in this project.
2.10.3 Are there any agreements between the investigator(s) and the sponsor(s) of this research that restrict publication of results from this research? If yes, provide details. No, this research will be sponsored by a grant from the Human and Horse Research Foundation.
2.11 HUMAN GENETICS RESEARCH
2.11.1 Does your research involve human genetic material? Yes ☐ No ☒
2.11.2 If yes, what are the ethical issues involved? (consult section 13 of the Tri-Council Policy statement) Click here to enter text.

SECTION 3. SUBMISSION CHECKLIST FOR INFORMED CONSENT

Complete this checklist and submit with the application.

Yes	Not applicable	
☒	☐	Identification of document as CONSENT FORM
☒	☐	Title of study
☒	☐	Identity and affiliation of researchers
☒	☐	Contact information of individual conducting the study
☐	☐	Invitation to participate in research
☐	☐	Assurance of voluntariness and right to withdraw without repercussions
☒	☐	Short description of the purpose of the study
☒	☐	Short description of the study design and how many participants are involved
☒	☐	Description of inclusion and exclusion criteria
☒	☐	Description of what the participant is being asked to do
☒	☐	Estimate of the participant's time commitment
☒	☐	Description of where the research will take place
☐	☐	Description of special items or other preparations required of the participant
☒	☐	Description of how anonymity will be handled

☒	☐	Description of how confidentiality of the data will be assured
☒	☐	Description of any necessary limitations of confidentiality protections
☐	☒	Description of the nature and probability of risks for participants
☐	☒	Description of the benefits and risks associated with participating in this research
☐	☐	Description of compensation that will be provided to participants
☒	☐	Declaration of any researcher conflict of interest
☐	☒	Description of any possible commercial outcomes of the research
☐	☒	Description of how participants will review transcripts of interviews
☒	☐	Description of how study results will be provided to participants
☐	☒	Permission requested for audio/video taping
☐	☒	Permission requested for use of quotations
☐	☒	Permission for future use of data in specified studies
☐	☒	Permission to re-contact participant for participation in future studies
☐	☒	How assent of participant will be sought when 3rd parties give consent
☒	☐	Signature statement indicating that information has been provided
☒	☐	Signatures of participant and person obtaining consent
☒	☐	Appropriate Reading comprehension level (normally Grade 8)
☒	☐	I understand that I can contact the UPEI Research Ethics Board at (902) 620-5104, or by email at reb@upei.ca if I have any concern about the ethical conduct of this study.
☒	☐	I have the freedom to withdraw at any time
☒	☐	No waiver of rights is sought
☒	☐	Signature and Date
☒	☐	I understand that I can keep a copy of the signed and dated consent form
☒	☐	I understand that the information will be kept confidential within the limits of the law
☒	☐	I have the freedom to withdraw at any time and/or not answer any question

SECTION 4: FOR RESEARCH APPLICATIONS THAT MUST ALSO BE REVIEWED BY THE HEALTH PEI REB

UPEI researchers who wish to conduct research that involves patients, staff, resources or data under the auspices of the Health PEI and the Department of Health and Wellness must submit their UPEI REB application for review by the UPEI Research Ethics Board and the PEI Research Ethics Board before the research begins. **UPEI researchers are no longer required to submit a separate Health PEI REB application to the Health PEI REB.** However, researchers must use the following submission process for review of these files:

1. Submit one e-copy and one hard copy of the following documents to reb@upei.ca, UPEI Research Services, 200 Kelley Memorial Building:

- UPEI REB application;
- All applicable participant consent/assent forms;
- Letter of information to the participant;
- Advertisement and/or other recruitment notice;
- Telephone or other scripts used for participant recruitment;
- Questionnaire/s, measurement instruments or other survey tools;
- Copy of letters of agreement or support from impacted Health PEI services (if applicable);
- Data map/s if the research includes the analysis of one or more large datasets;
- Letter to primary care provider (if appropriate) (contact the Health PEI office with questions);
- CV of the principal investigator;
- Study budget
- Copy of study protocol, if one exists from submission to an alternate REB
- TCPS2 certificate for PI must be included. It is recommended that other team members also complete the tutorial and submit a copy of their TCPS 2 certificate;
- Confirmation of Supervisor's Review (if applicable)
- Submission checklist

2. The UPEI REB will review the submitted documents for completeness and to ensure that the proposed protocol is in compliance with the UPEI REB policy. Complete applications will be forwarded by the UPEI REB to the Health PEI REB for review by that committee**.**

Please note that UPEI researchers must send their applications and associated documents directly to the UPEI REB - not to the Health PEI REB.

3. Applications that do not involve more than minimal risk are typically considered appropriate for expedited review by the Health PEI REB. Studies that are eligible for expedited review can be submitted at any time.

Applications that involve more than minimal risk must be reviewed by all members of the Health PEI REB. The Health PEI REB meetings are generally held monthly, with the exception of July and August, when only one meeting may be held. The deadline for full board submissions is approximately three weeks prior to the meeting date. A list of the Health PEI REB meeting dates and submission deadlines can be found at http://www.healthpei.ca/reb

4. The Health PEI REB will write to inform the UPEI researcher and the UPEI REB of their decision. UPEI REB will accept the decision of Health PEI REB.
A more detailed explanation of the UPEI/Health PEI REB streamlined review process is available at http://www.upei.ca/research/research-services/research-certifications/research-ethics-board

SUBMISSION CHECKLIST FOR APPLICATIONS TO BE SUBMITTED TO UPEI REB AND TO HEALTH PEI REB

Title of Study:
PI:

YES	N/A	
☐	☐	UPEI Research Ethics Board application form
☐	☐	Participant Consent forms
☐	☐	Letter of Information for participants
☐	☐	Advertisement and/or other recruitment notices
☐	☐	Telephone or other scripts used for participant recruitment
☐	☐	Questionnaire/s, measurement instruments or other survey tools
☐	☐	Copy of letters of agreement or support from impacted Health PEI services
☐	☐	Data map/s if the research includes the analysis of one or more large datasets
☐	☐	Letter to primary care provider
☐	☐	CV of the principal investigator
☐	☐	Study budget
☐	☐	Copy of study protocol, if one exists from submission to an alternate REB
☐	☐	TCPS2 certificate/s
☐	☐	Confirmation of Supervisor's Review
☐	☐	Submission checklist

Letter of informed Consent for the study: Psychophysiological effects of Equine-assisted therapy on horses and in veterans diagnosed with post-traumatic stress disorder (PTSD)

Submission Date: August 1, 2019

Laurie A. McDuffee, DVM, PhD, DACVS Principal Investigator, University of Prince Edward Island

You have been invited to participate in this research study, which is intending to explore the efficacy of EFP on human-horse dyads through changes in measures of stress hormones and PTSD symptoms. The proposed study is a prospective cohort study consisting of an 8-week EFP intervention for combat veterans with PTSD. This study is novel in the representation of paired data from the human-horse dyad.

You are free to ask questions at any time before, during or after you agree to participate in this study. You can contact members of the research team from UPEI: Dr. Laurie McDuffee by telephone at (902) 566-0996, or by e-mail at: lmcduffee@upei.ca , or Dr. William Montelpare by telephone at (902) 620-5186, or by e-mail at: wmontelpare@upei.ca They will do their best to respond to each of your questions.

Post-traumatic stress disorder (PTSD) is a psychiatric disorder that occurs in persons after experiencing or witnessing a traumatic event. The condition is characterized by intrusive thoughts, avoidance, negative thoughts and feelings, and over arousal, and is associated with numerous comorbidities including depression, anxiety, chronic pain, hypertension, and substance abuse-related issues. PTSD can be a chronic and disabling condition, affecting all areas of a person's well-being. Although observed across the general population, PTSD is particularly prevalent in military veterans who have been exposed to combat duties.

Animal assisted therapy (AAT) is used to promote the mental and physical health of humans. Previous studies using animal assisted therapies for veterans with PTSD have demonstrated positive effects on symptoms of PTSD and comorbidities, such as anxiety and depression. One particular field of interest is the use of equine assisted activities and therapies (EAA/T) for treatment of PTSD in military veterans. Horses provide a unique therapeutic experience for veterans diagnosed with PTSD due to their large size and nature as a prey animal. The interaction between veterans and horses can help participants improve communication skills and confidence in a way that appeals to the veteran’s sense of adventure and achievement.

One particular form of EAA/T, equine facilitated psychotherapy (EFP), has been observed as a potentially valuable treatment alternative for PTSD. A wide variety of programs have been developed in the United States and Canada, incorporating horses on the ground and with riders. The Mindful Warriors Equine Therapy Program, for example, uses EFP as intervention that incorporates horseback riding and psychotherapy to help veterans regulate their physiological responses to stress and other emotional states, as well as to recognize their relationship patterns and deepen connections with others through the relationship with the horse.

What is the purpose of the research study?

The purpose of this study is to to explore the efficacy of equine facilitated psychotherapy (EFP), on human-horse dyads through changes in measures of stress hormones and PTSD symptoms.

Why have I been asked to participate?

You have been asked to participate because you are among the specific target cohort identified within the scope of this research program.

Do I have to take part in this research process?

Your participation in any part of this research is voluntary. You may refuse to participate in this research without giving any reason. You have the option to withdraw from the research process at any point without giving any reasons. If you choose to withdraw from this research, any data you have already provided may be retained and used for the purposes of this research.

What will I have to do if I agree to participate? If you choose to participate, we will ask you to participate in an 8-week program at Serene View Ranch, an EAGALA certified facility. Each participant will be paired with an individual horse for the 8-week period -each session is 1 hour in duration. The EFP sessions will involve grooming of horses and leading horses in an arena.

Measurement of symptoms of PTSD in veterans will be collected at three predesignated time points using four standardized surveys: the Multidimensional Anxiety Questionnaire (MAQ), the Beck Depression Inventory (BDI-II), and the STAXI-2 State Anger scale which assesses the intensity of anger as an emotional state at a particular time, and the PTSD Checklist (PCL-5) which is a 20-item self-administered assessment designed to measure symptoms of PSTD. The schedule for data collection will be prior to the first EFP session on day 1, after four sessions of EFP, and at the end of 8 sessions of EFP. In addition, veterans will complete a self-perceived well-being scale consisting of a 10 item scale ranging from unwell to well with verbal anchors at the start and end of each EFP session to evaluate state changes in mood.

Objective measurements of Heart Rate Variability (HRV), cortisol and oxytocin will be collected from human subjects using Polar Heart Rate Monitors and from passive drool samples, respectively. HRV data will be collected 30 minutes prior to each session during a resting period (baseline) and throughout each session. Specifically, heart rate monitor recording will be started when the monitors are placed on each individual 30 minutes before the therapy sessions begin, continued during the entire 1 hour EFP session, and for an additional 30 minutes after EFP, for a total of 2 hours. For each person, 10 minutes of HRV data before each session, 10 minutes during grooming of horses, 10 minutes at the midpoint of the time spent with the horses, 10 minutes during leading, and 10 minutes after the session will be collected for a total of five time periods of HRV for analysis. Passive drool will be collected 30 minutes prior to each session during a resting period (baseline) and at the end of each session. Passive drool will be sent to Salimetrics, LLC for cortisol and oxytocin analysis.

The items are standardized and will refer to specific constructs that have been thoroughly tested.

This information will enable the overall aim of the study to be achieved i.e. to understand the characteristics of equine facilitated psychotherapy (EFP) as a treatment modality in Veterans with PTSD.

Are there any possible disadvantages from participating?

There are no foreseeable risks involved in participating. A website will be provided by the technical support team at the University of Prince Edward Island to ensure that all explanatory information pertaining to this study is available to you throughout the duration of the study. If there is any unexpected discomfort, disadvantage or risk to you during the course of this clinical assessment process please bring it to the attention of either Dr. Laurie McDuffee [(902) 566-0996; email lmcduffee@upei.ca], or Dr. William Montelpare [(902) 620-5186; e-mail wmontelpare@upei.ca], to help you find support.

What if something goes wrong?

There are no known risks or harm with this research process. If you are harmed by taking part in this research process, there are no special compensation arrangements. If you have any problems with the ethical conduct of this study please send an e-mail to reb@upei.ca or call (902) 620-5104.

What are the possible benefits from taking part?

The data will contribute to the knowledge base and inform the research support team about the characteristics related to PTSD and EFP in the selected cohort.

Will my participation be kept confidential?

Yes, all information collected will be kept strictly confidential. During the study, Dr. Laurie McDuffee and members of the research team will have access to data that you submit. Your response details that you submit will be stored in a password-protected computer. Your survey responses will not be held together with any personal details. Data will be stored on the University of Prince Edward Island firewall protected secure server that is only accessible via password for security and safety. After finishing this study the data will be stored in password protected computer of the Project Principal Investigator (Dr. Laurie McDuffee) for 5 years and then destroyed according to the University policy on data protection.

What will happen to the results of the research project?

A summary of the findings will be available to you as part of the final report to the Human and Horses Research Foudation. Likewise, the research findings will be published in a peer reviewed journal such as The Journal of Military Veterans and Family Health, American Journal of Health Behavior, or Journal of Veterinary Behavior. In addition the knowledge dissemination will occur in the form of presentations at international conferences such as Canadian Institute for Military Veterans Health Research, International Society of Equitation Science, and International Veterinary Behavior Meeting..

NEITHER YOU NOR YOUR SPECIFIC RESULTS WILL BE IDENTIFIABLE IN THIS REPORT. The results of the study will be submitted for publication in peer reviewed journals and presented at academic and professional conferences.

You may copy this information sheet for future reference.

Some basic guiding principles for the partnership between the researchers and the participants

I have read the information sheet for this study and have been given permission to print any information I wish. I have also been provided a contact number of the Principal Investigator and an invitation to ask questions about the study or my participation in the study.

I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my legal rights being affected and I give consent for any data already given to be retained and used.

I understand that I will not benefit financially if this study leads to the development of education and training or future research/education/technological developmental outcomes.

I know how to contact the study team if necessary. I understand that I can contact the University of Prince Edward Island Research Ethics Board at (902) 620-5104, or by email at reb@upei.ca if I have any concerns about the ethical conduct of this study.

I understand that by responding to the surveys and signing this letter of informed consent that I am agreeing to participate in this study.

I understand that a written summary of the findings will be available to participants through reports produced by the study team and disseminated via professional and academic journals and conferences.

The research study will also help to reduce the stigma associated with a veteran's mental health issues and it is anticipated that with the data received, new activities related to mental health for veteranss will be developed. It is anticipated that the outcomes of such a study will expand across the boundaries of all health professionals, not just those involved with the cohorts identified in this particular study.

It is expected that results of these investigations will provide essential information about the PTSD phenomenon based an accurate and fundamental source of information for participants.

This information sheet is yours to keep. You can save or print a copy of this consent form for your records.

Signed by: _____

Print Name: _____

Witnessed by: _____

Print Name: _____

Date: _____

C. Letter of Support

SERENE VIEW RANCH PSYCHOLOGICAL SERVICES
Mailing Address: P.O. Box 24076, Stratford, PE C1B 2V5
Location: 174 Pickles Lane, Alexandra, PE
Telephone: 902-393-3829; Fax: 902-569-8197
Website: www.sereneviewranch.com

To: Dr. Laurie McDuffee

From: Caroline LeBlanc

RE: Research Proposal

Date: July 25, 2019

Dear Dr. McDuffee,

The following is to confirm that Serene View Ranch, Psychological Services, is interested in participating in the research that will be conducted by yourself under the HHRF. The research proposed, titled Psychophysiological effects of Equine Assisted Therapy in Horses and Veterans: Exploring the influence of Post Traumatic Stress Disorder, fits within the area of work that SVR does with Veterans. Research in this area is limited, but interest in the therapeutic benefits of horses is on the rise, as programs are being developed across the world.

Please let us know if there is anything else that we can do. We can be reached at 902-393-3829.

Sincerely,

Caroline LeBlanc
Registered Psychologist

Clinical Team
Derek Anderson, MSW; Tara Costello, M.A., Randell Duguid, MSW; Sandra Fraser, RN;
Barbara Jones, M.A.; Alan Kostyniuk, M.Ed., Caroline, LeBlanc, M.A.; Donna MacLeod, OT;
Danny Miles, M.A.; Nancy Montgomery, M.A.

D. Animal User Protocol and Owner Consent

Revised - March 2017

ANIMAL OWNER CONSENT FORM

APPENDIX A - Research

CONSENT FORM FOR ANIMAL OWNERS

You have been invited to enter **(**_____**)** in a research project entitled **(**Psychophysiological effects of Equine-assisted therapy on horses and in veterans diagnosed with post-traumatic stress disorder (PTSD)**).** Please read this form carefully, and feel free to ask questions you might have.

Investigator(s): Laurie McDuffee, Health Management, 902-566-0996
William Montelpare, Applied Human Sciences

Funding Source(s): Human Horse Research Foundation

Purpose and Objective of the Study: To determine the effect on the wellbeing of horses and humans when Equine Facilitated Psychotherapy (EFP) is used as PTSD therapy for Veterans

Knowledge Transfer: The knowledge gained from assessment of the behavioural and physiological state of the horses will be written up as research publication and will be presented at an international conference.

Potential Benefits: If certain horses are found to be highly stressed during the sessions, interventions can be instituted or variations to their scheduling in sessions may be applied.

Description of the Procedures: Horses will be instrumented with a heart rate monitor which goes around the girth area, and will be recorded with a camcorder during the sessions. At 2 different time points (before the start of the session and after the completion of the session) a gauze sponge will be placed in the corner of the horse's mouth to obtain saliva and blood will be collected from the jugular vein. Horses will have the same procedures conducted every session for the duration of the study.

Potential Risks and Discomforts: Horses tolerate the HR monitor belt well, and they have minimal aversion to the collection of saliva or blood collection.

Financial Implications: There will be no cost to you for entering your animal in this study. You will not be charged for any of the procedures performed solely for the study's purposes. All unrelated costs for diagnosis, management and treatment of your animal are your responsibility. You will receive no reimbursement for entering your animal in this study.

Confidentiality: While absolute confidentiality cannot be guaranteed, every effort will be made to ensure that the information collected for this study is kept entirely confidential. Your name or that of your animal will not be attached to any information nor mentioned in any study report, nor be made available to anyone except the research team. Subject to any pertinent PEI government legislation, all information is strictly confidential. Results of this study are intended for publication in scientific journals and presentation at related conferences and workshops, but your identity or that of your animal will not be revealed."