INVESTIGATOR STUDY PLAN - REQUIRED

1. TITLE

Wildlife and Wellbeing: An Animal-Assisted Intervention for Veterans with PTSD

2. EXTERNAL IRB REVIEW HISTORY*

N/A

3. PRIOR APPROVALS:

Conflict of Interest (COI): N/A

Clinical Engineering Department: N/A

Biohazardous Agents:

According to the guidelines " An IBC registration is NOT required if: • The protocol ONLY involves sending human samples to the UMMHC clinical laboratories."

Radiation*:*

N/A

4. OBJECTIVES*

The purpose of this study is to examine the influence of Animal Assisted Intervention wildlife activities on veterans with PTSD. The specific aims of this study are to explore a series of wildlife animal-assisted interventions with 50 veterans who have PTSD/ PTSD symptoms in order to:

1. Determine the feasibility, safety and acceptability of the interventions to ensure adequacy of each intervention for a larger RCT. Outcomes will be measured by recruitment and retention, rate of adverse events, activity surveys and focus groups.
2. Obtain preliminary estimates of the wildlife AAI on physiologic and psychological well-being and assess relative efficacy of the three interventions. Outcomes will be measured by the PCL-5,[23, 24] Warwick-Edinburgh Mental-Well Being Scale,[44, 45] Speilberger State/Trait Anxiety Inventory[46] and Center for Epidemiologic Studies Depression (CES-D-10) scale.[47] Physiologic measures include heart rate variability. [49]
3. Obtain preliminary estimates of connectedness to nature and wildlife through the short-form Nature-Relatedness (NR-6)[50] and Human-Wildlife Bridging Feelings of Valuation Scale.[20]

5. BACKGROUND*

Introduction

Human-animal interactions within a variety of settings and populations have shown positive health benefits.[1] While the field of human-animal interaction is very promising there is need for a more rigorous evidence base.[2,3] Research on human-animal interactions has primarily been done with domesticated animals such as pets. We propose a novel approach using a series of wildlife activities for veterans suffering from PTSD following their military duty. The activities will be

conducted primarily within settings of wildlife rehabilitation and sanctuary. Our belief is that placing veterans in a healing environment where they can connect with animals that have also suffered loss and trauma may foster healing in the veterans themselves.

Significance: Human-Animal Interaction and Post-Traumatic Stress Disorder in Military Veterans

Animal-assisted intervention (AAI) has been defined as, "any intervention that intentionally includes or incorporates animals as part of a therapeutic or ameliorative process or milieu."[4, p.36] AAI includes the use of animals within specific therapeutic interventions (Animal-Assisted Therapy), less structured activities with animals (Animal-Assisted Activities) and use of trained animals to assist with daily activities (Service/Assistance Animals)[2] A meta-analysis of 49 studies using animal-assisted therapy found improved outcomes in four areas with moderate effect sizes: medical conditions, autism-spectrum symptoms, behavioral problems, and emotional well-being.[1]

One of the populations for which evidence supports possible AAI benefits is persons with post-traumatic stress disorder (PTSD). PTSD is a psychiatric disorder that can occur in people who have experienced or witnessed a traumatic event such as a serious accident, rape or other violent personal assault or war/ combat.[5] PTSD can affect anyone but has been particularly concerning among veterans suffering from wartime trauma. The prevalence of PTSD in veterans who served in recent wars in Iraq and Afghanistan ranges from 13.5-30% with an estimated 500,000 U.S. troops diagnosed with PTSD.[6] Symptoms of PTSD include intrusive thoughts or flashbacks to the traumatic event, avoiding reminders of the event such as people or places, negative thoughts or feelings, and arousal/ reactive symptoms such as irritable outbursts and self-destructive behavior.[5] PTSD is potentially a very debilitating condition that is associated with a higher risk of suicidal behavior, particularly among young, female and rural veterans. In addition to suicide, struggles with substance abuse and homelessness are significant problems for the population of veterans with PTSD.[6] Stigma is a major barrier to receiving treatment for PTSD; studies suggest that less than half of veterans with PTSD seek treatment within the first year.[7] Animal-assisted interventions have been utilized as complementary approaches that may alleviate this barrier due to “the nonjudgmental nature of human-animal interactions.”[7]

A systematic review conducted in 2015 found 10 studies on the use of AAI in trauma using dogs, horses and/ or farm animals. Only two of these focused on war trauma. The studies suggested that AAI was a promising complementary therapy, particularly in reducing PTSD symptoms, depression and anxiety, but that more rigorous studies are needed.[2] A review on the use of service dogs in veterans with PTSD found that although canine assistance was an encouraging complementary modality there was a need to determine best practices as well as challenges with service dog availability and cost.[6] In sum, HAI offers a promising approach for individuals suffering from war trauma but additional research is needed.[6,8,9] Given the practical challenges obtaining trained service dogs, it will be important to study modalities with other animals.

Scientific Premise: Wildlife and Health

The contemporary human disconnect from nature is an increasing health concern.[10,11] A growing body of literature supports favorable physiological, psychological and social health benefits from nature contact[10,11,12,13] Although there is promising literature on the benefits of both nature *and* animals, few studies have explored human interactions with animals that inhabit natural settings, or wildlife. The majority of HAI studies have focused on domesticated animals. Yet there are

promising accounts of human-wildlife interactions. Brock et al. distinguish between everyday and iconic wildlife.[14] *Iconic* wildlife experiences have been studied with individuals on wildlife tours with reported enhanced well-being and psychological benefits.[15] Everyday wildlife encounters such as home bird feeding may have human benefit.[12]

One important example of everyday wildlife interaction is bird feeding/ watching. Bird feeding has been linked with positive psychological benefits through feelings of pleasure and increased connectedness to nature. Self-reported well-being was associated with increased species diversity at feeder and familiarity with different species.[12] A neighborhood modeling study in the United Kingdom linked afternoon bird abundance (time of day when people were more likely to be outdoors experiencing birds) with reduced self-reported depression, anxiety and stress.[16] Brock et al. found that individuals who fed birds developed a "warden attitude" of concern for the birds that visited their own feeder.[14] A survey of 1291 bird-feeding hobbyists found that among the reasons for feeding birds were bringing nature and beauty to one's area (84%); wanting to help birds (79%) and relaxation or therapy (65%)[17] A bird feeder intervention with nursing home residents was found to increase perceptions of happiness, being active and having control over life.[18] Interestingly, the first formal maximum-security prisoner-canine program developed when staff noted the positive benefits experienced by prisoners that found and cared for an injured bird.[19] Thus, studies suggest that both wildlife viewing and providing wildlife care have therapeutic value.

Preliminary Data

Our study of visitors to a wildlife sanctuary demonstrated significantly increased emotional connection to both predator and nonpredator species.[20] Connectedness with wildlife is important because connection to nature is linked with higher perceived happiness.[12, 21] Specifically, findings suggested that participants had a significantly stronger emotional connection to moose as compared to coyote at baseline but that both moose and coyote scores increased significantly from pre to post visit. The study also tested a new instrument developed by the PI to measure emotional connection to animals which demonstrated good internal validity (Cronbach's alpha=.837-.940).[20] Increased emotional connection toward both valued and dis-valued species suggests that wildlife encounters may increase appreciation for diverse species which is important for balanced ecosystems.[20] Additionally, the findings suggest that learning about wildlife at the sanctuary reinforced and expanded attitudes and planned behaviors toward spending more time outdoors as well as environmental/ wildlife stewardship for both children and adults.[20] Thus, in addition to individual benefits, experiences with wildlife may hold broader potential for improving human health through fostering positive attitudes toward wildlife and habitat conservation.

Theory-Guided Intervention: Wildlife Immersion Activities

The study will be guided by the PI's theory of transcendent pluralism which is grounded in mutually evolving human and ecological dignity.[20, 31, 32] Wildlife experiences are viewed as pluralistic encounters that influence wonder and transcendence. In many Native American traditions each species of animal is viewed as having its own qualities that offer teachings for humans.[33, 34] Thus a variety of species may meet different human needs.

The activities that comprise the interventions will be framed within the concept, "Embodied spatial-temporal interaction", which emerged from the PIs prior study on wildlife rehabilitation.[35] Spatial territory is a core need for animals and must be respected when conducting AAI to avoid animal stress. Engagement in shared wildlife space requires

attentiveness to one's own spatial relationship to the animal. Safe space is also important for humans. There is a permeable boundary between humans and wildlife.[36] Wildlife rehabilitation and sanctuary care offer a healing window across this boundary. Study activities will be guided by experts so that the appropriate boundaries in each setting are maintained. Activities will also be framed within the natural rhythms of the seasons to be in synchronicity with animal needs. For example, spring is when baby wildlife may be orphaned and require human care. Thus, each intervention for this study is designed as an *immersion* activity experience within the space of a wildlife setting rather than a discrete action. The experience occurs in a wildlife-rich space and may include multiple interactions with diverse animal species over a period of time. **We define a wildlife immersion activity as an embodied spatial-temporal experience in which human participants enter a space (setting) in which they consciously engage with wildlife in a manner that affirms the dignity of both human and animal with respect for natural rhythms.** Wildlife immersion experiences are designated as animal-assisted activities (in contrast to animal-assisted therapy which entails formal therapeutic treatment).[2]

6. INCLUSION AND EXCLUSION CRITERIA*

Inclusion criteria:

- Veterans with PTSD/PTSD symptoms (per self report)
- Vaccination status for Covid-19 as:
    - Fully vaccinated against Covid-19 and up to date with booster, which is defined by the CDC (as of May 6, 2022) as:
        - Initial vaccination:
            - 2 weeks after second dose in a 2-dose series, such as the Pfizer or Moderna vaccines, or
            - 2 weeks after a single-dose vaccine, such as Johnson & Johnson's Janssen vaccine
        - PLUS: one booster, when eligible

    OR
    - Partially vaccinated against Covid-19 and willing/able to (a) complete a home antigen test for Covid-19 on the morning of each activity and report results to the PI prior to transportation departure and (b) willing to wear a mask during transportation to and from the activity
- Age 18-70
- Comfortable interacting with animals
- Sufficient mobility to walk or navigate wheelchair up to one mile at leisurely pace
- Cognitive ability to complete assessments
- Service/ support animals are permitted as long as they meet the following criteria: the animal must be leashed, housebroken and with sufficient training that the owner has control over its barking and any other behaviors that would threaten the safety of other visitors or animals.
- Participants with visual or hearing impairments must have corrected vision and hearing through glasses and/ or hearing aid(s).
- No active addiction or intoxication as determined by 30 days or more free from drugs or alcohol abuse

- Willing to refrain from alcohol and illicit substances before and during activities
- No severe immunosuppression or other conditions with advisement by health care provider to limit or prevent contact with animals and birds
- No severe outdoor allergy. Not currently enrolled in the Veteran's Treatment Court program

Exclusion criteria:

- Veterans without PTSD/PTSD symptoms (per self report)
- Not fully vaccinated and up to date against Covid-19
  OR
  - Partially vaccinated against Covid-19 and not willing to (a) complete a home antigen test for Covid-19 on the morning of each activity and report results to the PI prior to transportation departure and (b) willing to wear a mask during transportation to and from the activity
- Age <18 or >70
- Not comfortable interacting with animals
- Not sufficiently mobile to walk or navigate wheelchair up to one mile at leisurely pace
- Cognitively unable to complete assessments
- Service/ support animals that do not meet the following criteria: leashed, housebroken and with sufficient training that the owner has control over its barking and any other behaviors that would threaten the safety of other visitors or animals.
- Participants with visual or hearing impairments who do not have corrected vision and hearing through glasses and/ or hearing aid(s).
- Active addiction or intoxication as determined by < 30 days free from drugs or alcohol abuse
- Not willing to refrain from alcohol and illicit substances before and during activities
- Severe immunosuppression or other conditions with advisement by health care provider to limit or prevent contact with animals and birds
- Severe outdoor allergy
- Currently enrolled in the Veteran's Treatment Court program

7. STUDY-WIDE NUMBER OF SUBJECTS*
N/A

8. STUDY-WIDE RECRUITMENT METHODS*
N/A

9. STUDY TIMELINES*
The study timeline is outlined in the table below. We anticipate enrolling 30 participants in year 1 of the study and 20 participants in year 2 of the study. Each participant will be in the study for 6-8 months from enrollment to final data collection. The timing of activity schedule may be modified slightly based on feedback of study advisory committee to be convened.

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Study Timeline (2 year)
***Note: we are now in no-cost extension until Dec. 2022 due to Covid delays**
Updated Dec. 18, 2018

	Setting	Year 1 (N=30 of 50)						Year 2 (N=20 of 50)					
		Mar	Apr-June	July-Aug	Sept-Oct	Nov-Dec	Jan-Feb	Mar	Apr-June	July-Aug	Sept-Oct	Nov-Dec	Jan-Feb
IRB Initial Approval		X -in process											
IRB Renewal						X						X	
Hire & train research staff		X	X										
Convene Advisory Committee		X						X					X
Recruitment		X	X 25%	X 50%				X	X 75%	X 100 %			
Introductory Forest walk *Time 1/Time 2*	Harvard Forest		X						X				
Wildlife Activity I Wildlife rehab *Time 1/Time 2*	NEWC		X						X				
Wildlife Activity II Wildlife observation *Time 1/Time 2*	MWP			X						X			
Wildlife Activity III Bird feeding *Time 1/Time 2*	Mass Aud. & Soldier On				X	X*					X	X*	
F/U interview/ phone survey							X						X
Data Analysis						X	X					X	X

**Participants will have option to continue bird feeding after study completed*

10. STUDY ENDPOINTS*

- The primary outcome measures are from study Aim I: Feasibility and safety of intervention will be measured through ongoing observation and safety logs and monitoring of recruitment/ retention. Acceptability will be assessed with activity evaluation surveys, focus groups at study conclusion and a follow-up personal interview/ phone call to assess bird feeder use.

- The secondary outcome measures are from Aim II and Aim III: Psychological well-being will be assessed at baseline and after each activity through: Warwick-Edinburgh Mental-Well Being Scale (14 item; α=.91)[44, 45], Speilberger State/Trait Anxiety Inventory (6 item; α=.82)[46] and Center for Epidemiologic Studies Depression (CES-D-10) scale (10 item; α=.70).[47] We will measure physiological parameters (heart rate via wearable wrist biosensor)[48] at baseline with F/U heart rate both before and after each activity. We will

also obtain the PCL-5 at baseline and a follow up measure of the PCL-5, at study conclusion.[23, 24] Connection to nature and wildlife will be measured at baseline and after each activity through: the short-form Nature-Relatedness (NR-6) (6 item; α=.85-.96)[50] and Transcendent Feelings of Animal Valuation Scale developed by PI (7 item; α=84-.94).[20] Qualitative assessment will include an animal observation journal exercise during the Maine Wildlife Park activities.

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There are no safety endpoints.

11. PROCEDURES INVOLVED*

Approach

The feasibility nature of this study offers flexibility to evaluate a series of immersion activities. We will use a crossover design in which each participant receives a sequence of 3 wildlife-immersion activities and serves as his or her own control.[37] The use of crossover designs has been suggested for future AAI studies.[3] The intervention will include an introductory forest walk followed by 3 wildlife immersion activity experiences in different settings that offer different ways to experience wildlife. All activities will be guided by field experts and include education to ensure safety for human subjects as well as animals. Wildlife education programs have been shown to reduce fear and enhance self efficacy about managing encounters with wildlife.[38, 39] Each activity will be conducted twice to minimize potential anxiety and novelty effects. Activities will be planned in small groups (up to 10 participants) to provide more concentrated experience at facilities and peer support. We will endeavor to maintain same groups throughout although logistical modification may sometimes be needed.

Activities (see protocol below for detailed outline) include: **Introductory Forest Walk**: A guided forest walk will be conducted to control for effects of nature alone; **Wildlife Immersion Activity I**: Participants will experience wildlife through a wildlife rehabilitation setting in which they engage in activities such as feeding baby animals and enrichment; **Wildlife Immersion Activity II**: Participants will experience wildlife through observation of iconic wildlife at a wildlife park/ sanctuary and accompanying game keepers during feeding/enrichment; and **Wildlife Immersion Activity III:** Participants will experience wildlife in the natural setting through bird feeding and watching. This activity is designed to transition to a sustainable home activity that veterans can continue following study conclusion. After an initial training at Mass Audubon we will provide individual bird feeders to participants as well as community bird feeders at the indicated Soldier On facilities. Bird identification education and books will be provided. All settings also have self-guided educational displays so free time will be included in each session to facilitate each participant's transcendent inquiry as part of the wildlife immersion experience. The time between each set of activities will be spaced by at least one week as a washout period to reduce any carryover effect.[37] We anticipate that the forest walk will show a small improvement over baseline measures at enrollment (due to nature effect) and that each animal activity will show an additional improvement above the forest walk (nature plus animal).

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Intervention Protocol (to be refined with Advisory Committee)

**Physiological = physiological measures (heart rate)*
Instruments= (Warwick-Edinburgh Mental-Well Being Scale, Speilberger State/Trait Anxiety Inventory, CES-D-10; NR-6; Human-Wildlife Bridging Feelings of Valuation Scale; and activity evaluation survey).

	Location	Education	Activities	Animals Involved	Pre-Measure*	Post-Measure*
Screening					Inclusion Criteria	
					30-45 minutes	
Baseline					-PCL-5 -Consent -Demographics -Physio - -Instruments	
Time estimate					1 hour	
Introductory Forest walk						
Time 1	Harvard Forest	Forest overview/ ecology	Forest walk	Non-animal intervention	-Heart rate	-Heart rate -Instruments Post activity survey
Time estimate	2 hour drive each way	30 min.	1 hour *Followed by lunch*		5 min.	30 min.
Time 2	Harvard Forest	Native trees	Forest walk	Non-animal intervention	-Heart rate	-Heart rate Instruments -Post activity survey
Time estimate	2 hour drive each way	30 min.	1 hour *Followed by lunch*		10 min.	30 min.
Wildlife immersion activity I: Wildlife rehabilitation						
Time 1	New England Wildlife Center	-Facility overview -Wildlife rehabilitation principles	-Feeding baby animals* -Enrichment activities -Wildlife care **expert-guided activities integrated with routine*	Birds and small mammals such as squirrels	-Heart rate	-Heart rate -Instruments -Post activity survey

			care so not to cause extra animal stress			
Time Estimate	2 and ½ hour drive each way	1 hour	1 ½- 2 hours *Followed by lunch*		5 min.	30 min.
Time 2	New England Wildlife Center	-Human-wildlife interaction	As above	Birds and small mammals such as squirrels*	-Heart rate	-Heart rate Instruments -Post activity survey
Time Estimate	2 and ½ hour drive each way	1 hour	1 ½-2 hours *Followed by lunch*		10 min.	30 min.
Wildlife immersion activity II: Wildlife Observation						
Time 1	Maine Wildlife Park	-Sanctuary overview -Species info	-Observation -Accompany gamekeepers during feeding	30 species for observation (including moose, deer, bobcats, fox, owls, skunks, porcupine)	-Heart rate	-Heart rate -Animal journal -Instruments -Post activity survey
Time Estimate	4 hour drive each way	1 hour	2-3 hours *Followed by lunch*		. 5 min.	45 min.
Time 2	Maine Wildlife Park	-Animal Enrichment	-Observation -Accompany gamekeepers during enrichment -Individual animal observation exercise	30 species for observation (as above)	- -Heart rate	-Heart rate - Instruments -Animal journal (App. G) -Post activity survey
Time Estimate	4 hour drive each way	1 hour	2-3 hours *Followed by lunch*		10 min.	45 min.
Wildlife Immersion Activity III: Bird feeding/ watching						
Time 1	Mass Audubon Broad Meadow Brook	-Bird identification and feeding	-Nature walk with focus on identifying native bird species	-Birds	-Heart rate	-Heart rate -Instruments -Post activity survey

Time Estimate	1 ¾ hour drive each way	1 hour	1 hour		5 min.	30 min.
Time 2	At Soldier On Facilities (with Mass Audubon specialist)	-Bird feeding F/U -Birds of prey -Citizen scientist	-Observing birds at feeder -Observing birds of prey (with specialist)	-Birds	-Heart rate	-Heart rate -Instruments -PCL-5 -Post activity survey -Focus group (study conclusion)
Time Estimate	At Soldier On	1 hour	1 hour		10 min.	1- 1 ½ hours
Post study	Home bird feeding					-F/U interview/ phone call 4-6 weeks after final study activity
Time Estimate						15-20 min.
Time Estimate	8 weeks total; estimate of 10-15 minutes per day					

**Specific animals will be determined based on facility census and care routine.*

12. DATA AND SPECIMEN BANKING*
N/A

13. Data Analysis and Management*
Instruments described below are provided in the document entitled "Data Collection Forms and Surveys"

Scientific Rigor
Literature on HAI research has identified several methodological issues with recommendations to address these including: detailed procedures for future replicability, unbiased outcome measures, independent researcher/ intervention teams, provisions for animal welfare and human safety[3,9] and addressing novelty as a confounder.[40] Two additional concerns not appreciated in the literature are: (a) need to address nature itself as potential confounder due to health benefits from nature contact and (b) sustainability; i.e. many reported studies describe interventions that may not be feasible for participants to continue. Table 1 outlines our strategies to address these issues.

Table 1. Methodological Strengths

Issue	Strategy
Undocumented procedures	• Procedure protocol documentation with refinement for future RO1 study
Biased evaluation	• Inclusion of objective measures

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Researcher/interventionist overlap	• Separate research/ intervention staff
Animal welfare	• Wildlife veterinarian consultant • Expert-guided activities for best-practices • Animal care activities will be integrated with routine care • PI with wildlife rehabilitation experience
Human safety	• Facilities selected for expertise in educating novices • Education and expert-guided activities following all facility protocols • Additional measures described in human subjects section
Novelty as potential confounder	• Each activity repeated twice
Nature itself as possible confounder	• Preliminary measures taken after forest walk without animal intervention
Sustainability	• Settings with native New England habitat and animals • Home bird feeding/ watching activity that participants can continue • Use of wildlife facilities with public access that participants can visit in future.

Measures

We will utilize both quantitative and qualitative measures to assess parameters from study aims guided by a unitary-transformative paradigm of integrated bio-psycho-social-spiritual human needs.[41,42]

Aim I: Feasibility and safety of intervention will be monitored through ongoing observation and safety logs and monitoring of recruitment/ retention. Acceptability will be assessed with evaluation surveys after each activity, focus groups at study conclusion and a follow-up phone/ in-person interview to assess bird feeder use 4-6 weeks after final study activity. The activity and focus group questions will be framed using transcendental method, a cognitive approach developed by the PI and used in several prior studies.[43]

Aim II: Psychological measures will be conducted at baseline and after each activity to reduce learning effects. Psychological well-being will be assessed through Warwick-Edinburgh Mental-Well Being Scale (14 item; α=.91)[44, 45], Speilberger State/Trait Anxiety Inventory (6 item; α=.82)[46] and Center for Epidemiologic Studies Depression (CES-D-10) scale (10 item; α=.70).[47] We will also measure physiological parameters. Heart rate via wearable wrist biosensor will be measured at baseline and before and 5 minutes after each activity. Noninvasive stress markers such as heart rate are preferable as they reduce stress induced by collection and are more applicable in the field[49] as well as being consistent with a nature-focused intervention. We will also obtain a measure of PTSD symptoms through administering the PCL-5 at baseline and at study conclusion.[23, 24]

Aim III: Connection to nature and wildlife will be measured with the short-form Nature-Relatedness (NR-6) (6 item; α=.85-.96)[50] and Transcendent Feelings of Animal Valuation Scale developed by PI (7 item; α=84-.94)[20] at baseline and after each activity. Qualitative assessment will include an animal observation journal exercise during the Maine Wildlife Park activities.

Data management

Surveys with ID numbers will be conducted using pen and paper and collected by PI immediately afterwards. Quantitative data will be entered into SPSS version 24 by research assistant and/or PI using double data entry. Focus group audiotapes will be transcribed by a transcriptionist using Microsoft word files. All data will be stored in a password-protected institutional research drive with access limited to investigators and research assistant. Hard copies will be kept in locked file/office.

Analytic Plan

Sample size and power: Because pilot studies do not provide meaningful estimates of effect sizes for between-condition comparisons, due to the imprecision inherent in small samples[51,52] we base our proposed sample size of 50 participants – anticipated average of 10 per group – on pragmatics of recruitment, retention, and examination of feasibility, acceptability, and safety, providing important information for planning a future R01 study. Taking retention as an illustrative Aim 1 outcome, a 95% confidence interval is (35.5%, 64.5%) for a rate as low as 50% seen in the PTSD literature,[2] and (66.3%, 90.0%) for 80% retention. Dr. Smelson (Co-I) has a long standing relationship of working with Soldier On and has obtained follow up rates above 80% in other studies.[53] For Aim 2-3 analyses, we adjust the sample size for possible within-group correlation (intra-class correlation, ICC) using ICC=0.0105 from a prior study of mindfulness.[54] Applying the resulting design effect[55] of 1+.0105×(10-1)=1.0945 and 80% retention rate yields an effective sample size of 40/1.0945=36 participants. With an overall 0.05 Type I error rate and a Bonferroni correction for multiple testing (6 pairwise comparisons of the 4 activities), and 80% power, we will be able to detect a statistically significant mean within-participant between-activity difference in an outcome, e.g., anxiety, of 0.56 SD, where SD indicates standard deviation of within-participant change in the outcome. The corresponding detectable within-participant change from baseline to end of study or baseline versus each individual activity (no corrections for multiple testing), is 0.48 SD.

Statistical analyses:

Aim 1: To assess feasibility, we will estimate quantities relevant for study planning, including outcome standard deviations and within-participant and within-group correlations, and rates of attrition and missing data and their correlates. Acceptability of each activity will be assessed by tabulating evaluation surveys responses. Safety for each activity will be assessed via the per-participant distribution of incidents reported by severity. Analyses will be conducted for the full sample as well as by gender.

Aim 2: We will conduct preliminary intent-to-treat analyses comparing participant outcomes across activities and baseline using linear mixed modeling[56] with a random effect for participant group and accounting for within-participant correlation over time. In addition, the role of novelty for each activity will be estimated as within-participant differences in physiologic outcomes between the first and second time that activity is conducted. To the extent possible given sample sizes, we will adjust for participant characteristics predictive of missing data to reduce nonresponse bias.[57] Gender differences will be examined by including gender as a covariate, and its interaction with activity to explore effect modification; by necessity, the latter analyses will be exploratory.

Aim 3: Analyses parallel to those in Aim 2 will compare participants' connectedness to nature and wildlife across activities. Additional exploratory analyses will examine whether connectedness to nature and wildlife mediates between-activity differences in well-being in Aim 2 analyses.

Our estimates of retention, intra-group and within-participant correlation, standard deviations, and preliminary effect sizes and novelty effects, as well as expert opinion and literature, will inform the design of a future larger crossover study, including recruitment and selection of activities to be evaluated. This future study will randomize participants to ordering of activities (not feasible in this pilot study), permitting formal assessment and analytic treatment of possible carryover effects.[58] Interestingly, a meta-analysis suggests that effect sizes for AAI do not vary greatly by aspects of study design,[1] suggesting that estimates from our non-randomized-order pilot will be informative for future planning.

Qualitative analysis:

Qualitative data will allow us to capture a broader understanding of activity outcomes. Focus groups will be conducted and audiotaped by the PI and transcribed verbatim through a transcription service. Open-ended survey questions, F/U phone/ in-person interviews, reflective journaling from wildlife park and observation data will be entered into Microsoft word documents. Thematic analysis will be conducted by the PI through a rigorous multistage process. Raw data will be labeled with codes and analyzed at progressively higher levels of abstraction with insight into converging themes.[43] Reflexivity and measures of verification recommended by Creswell[59] will be utilized including prolonged engagement in field, triangulation of data and thick, rich description of participant responses.[27]

14. PROVISIONS TO MONITOR THE DATA TO ENSURE THE SAFETY OF SUBJECTS*

The principal investigator (PI) will be responsible for monitoring safety in this study. The PI will accompany study activities and maintain a safety log to report all incidents. Safety will be monitored on an ongoing basis. The safety log will be reported to the Safety Officer (Dr. Smelson) on a monthly basis. An interim analysis report will be conducted after Year I or as indicated by regulations. Serious adverse events will be reported to the Safety Officer and IRB immediately. Analysis of any adverse events will be conducted with modification of protocol if indicated. Further details are provided in the data and safety monitoring plan document.

Safety Log

	Date/ Time	No. of participants in activity	Safety incident	Etiology	Intervention for participant/ animal if needed	Modifications to protocol if needed	IRB Notification
Intro Forest Walk							
Time 1							
Time 2							
Wildlife Activity I							
Time 1							
Time 2							

Wildlife Activity II							
Time 1							
Time 2							
Wildlife Activity III							
Time 1							
Time 2							

Psychological Evaluation: The PCL-5 will be conducted at baseline and post study. A Soldier On mental health counselor will be available by phone during the administration of the PCL-5 test in case the test exacerbates any psychological symptoms. Psychological surveys will be entered within one week and monitored for significant increase. If any individuals have a high baseline score for anxiety or depression at study enrollment (as defined in literature) or a > 25% increase over baseline anxiety or depression scores, the participant will be referred for counseling at Soldier On via contacting the individual's Soldier On Case Manager. The case manager will be contacted via a secure email using "SEND SECURE" in the subject line. The email will include the participant's first name and last initial, name of test, normal test parameters, participant's score and comparison to baseline if applicable. Participants with any medical or psychological symptoms that occur during the activities will be referred to clinical services at Soldier On (which has clinical staff) or VA (which is located at same campus as Soldier On) via referral to the case manager. If any participants notify staff of exacerbation of psychological symptoms between activities, they will also be referred to Soldier On/ VA services. If an urgent medical or psychological issue occurs in the field, the study team would call 911 to have them transferred to closest hospital facility. The protocol will be finalized with the study advisory board once convened.

15. WITHDRAWAL OF SUBJECTS WITHOUT THEIR CONSENT*

Participants may be withdrawn from study without their consent if they exhibit behavior indicating active addiction or intoxication which is in violation of the inclusion criteria or if they engage in behavior which places any other participants or study staff at risk or if they engage in animal cruelty behaviors. Additionally they may be removed if they:

- Have an adverse event that requires stopping the research
- The research is canceled by the FDA or the sponsor
- Are unable to attend the activities as scheduled.

16. RISKS TO SUBJECTS*

Risks include:

- Potential loss of identifiable data
- Animal bite or scratch
- Exposure to animal disease

- Exacerbation of psychological symptoms
- Psychological distress due to seeing injured, dying or deceased animals
- Substance abuse exacerbation
- Triggering of psychological symptoms due to unexpected noises in external environment
- Tick bite during outdoor walk
- Allergy exposure
- Sun exposure
- Fatigue/ dehydration during activities
- Traffic accident in route to or from activity
- Contracting Covid-19

Protection against risks

Recruitment and Informed Consent

The PI will meet with each potential participant to review the study including potential risks and benefits. Participants will provide informed voluntary consent.

Participants will be accompanied during activities by the PI, a registered nurse. All wildlife-related activities will be preceded by education and guided by an expert in wildlife care. Risk-specific preventative measures will be taken as below. If any unexpected adverse events occur the event will be given immediate attention at the site (such as first aid if needed) and participant will be referred for appropriate medical or psychological care. The PI will bring a first aid kit and Narcan nasal spray as a precaution for all activities.

All study sites are < 19 miles from a local hospital (ranging from on site to 18.1 miles)

- Soldier On (On campus of VA Hospital in Pittsfield, MA)
- Harvard Forest-Athol Memorial Hospital (4.2 miles)
- Mass Audubon Broad Meadow Brook- UMass Memorial Medical Center (4.9 miles)
- Maine Wildlife Park-Central Maine Medical Center (18.1 miles-highway interstate travel)

Confidentiality: The following steps will be taken to ensure that all patient data remain confidential.

(1) *Use of numeric identifiers:* To ensure confidentiality, study assessments and electronically stored data will be identified only by a unique identifier. The master list linking the patient ID to the patient's identifying information will be maintained in a separate file and will be destroyed at the conclusion of the study. Signed consent forms will be kept in locked filing cabinets and will only be accessible to the PI and staff listed on the IRB approval.

(2) *Data storage*: No identifying information will be stored with survey responses, or within the analytic database. All paper data collection documents will be stored in locked file cabinets within locked offices that are accessible only to the project investigators and staff. Signed consents will be kept in a separate file from participant data. Access to the electronic data will be restricted to investigators and research staff using a designated research drive. Electronic data will be password protected to guard against unauthorized access.

(3) *Staff training*: All project staff will pass the CITI exam on ethical conduct of research. Any newly hired study staff will pass the web-based CITI exam as required by the University of

INVESTIGATOR STUDY PLAN - REQUIRED

Massachusetts Medical School Institutional Review Board for the Protection of Human Subjects. In addition, study staff will receive training and supervision regarding patient confidentiality. This training will be directed by Dr. Perry. The training will address the rights of patients to keep participation decision (yes or no) and all assessment data private and confidential. Training will also emphasize that discussion or disclosure of *any* information obtained from research participants during the course of the study is strictly prohibited. Prior to having any direct contact with research participants, the project assistant will receive training in recruitment and assessment procedures.

(4) *Handling of published data and reports*: Published data derived from this study will consist of statistical analyses collapsed (averaged) across participants. Qualitative data will contain direct quotes that participants have shared but no personable identifiable information will be linked to the quote. Under no circumstances will data from individual participants be identifiable in reports or published manuscripts.

Risk	Protective Measures
➢ Potential loss of identifiable data	➢ As described above.
➢ Animal bite or scratch	➢ Proper instruction prior to activities ➢ Follow facility protocols ➢ In the event of incident, first aid will be applied and participant will be referred to VA facility at Soldier On for follow up ➢ PI will undergo wilderness first aid course prior to study initiation
➢ Exposure to animal disease	➢ Use of gloves in wildlife veterinary hospital ➢ Follow facility protocols ➢ No activities with animals in isolation ward ➢ No handling of raccoons due to being rabies vector ➢ Exclusion of individuals with severe immunocompromised status ➢ Instructions for handwashing provided
➢ Exacerbation of psychological symptoms	➢ The PCL-5 test will be administered by the PI, a registered nurse, with a mental health clinician from Soldier On available by telephone in the event that any individuals develop psychological symptoms when taking the test ➢ Ongoing assessment by PI, RN ➢ An action plan will be developed with Soldier On for acute referral for any psychological distress; for stable symptoms we will notify the individual's case manager at Soldier On for referral to appropriate services including VA located by Soldier On; for acute emergency in

	the field PI will call 911 for patient to be brought to local ED. The case manager will also be notified if any field emergencies occur.
➢ Psychological distress due to seeing injured animals	➢ Animals on exhibit at Maine Wildlife Park are largely healthy ➢ At New England Wildlife Center we will focus activities primarily on healthy babies and animals with stable injuries.
➢ Substance abuse exacerbation (we anticipate some of population will have co-morbidities of substance abuse)	➢ Inclusion criteria of 30 days or more free of drugs or alcohol abuse and willingness not to use substances before or during activities ➢ Participants will be instructed not to use substances before or during activity trips; if any participants arrive for activity with signs of being under the influence of substances they will be asked to stay home that day; if any participants become impaired due to substance use during activities they will be asked to stay near van under observation of Soldier On project assistant. ➢ If any participants notify staff of exacerbation of psychological symptoms between activities, they will be referred to Soldier On/ VA services via notification of case manager. ➢ If any substance abuse exacerbation occurs during the activities participants will be referred to Soldier On/ VA services via notification of case manager. ➢ If any participant becomes physically or cognitively compromised the PI will call 911 for transport to local ED. ➢ PI will carry Narcan nasal spray in the event of participant overdose; PI will undergo training prior to study implementation
➢ Triggering of psychological symptoms due to unexpected noises in external environment.	➢ Due to the potential for distant gunfire from a rural gun club or seasonal hunters near the Harvard Forest (as well as a wide range of possible noises in any public environment) we have included that risk in the consent form and added a question to the activity evaluation regarding stress from environmental sounds/ events. Additionally, the PI has contacted the gun club to ascertain that no large scale target shooting events are scheduled during the times when the study activities will take place.

➢ Tick bite during outdoor walk	➢ PI will bring tick spray on all activity trips and will encourage use by each participant ➢ Participants will be instructed to monitor self for tick bites following activity and to call VA MD if any bites occur
➢ Sun exposure	➢ Although outdoor activities will primarily be in shaded areas PI will provide participants with sunscreen as a precaution
➢ Allergy exposure	➢ Participants with severe outdoor allergies excluded; participants with mild-moderate allergies encouraged to take medication prior to outdoor activities
➢ Fatigue/ dehydration from activities	➢ A boxed lunch will be provided each day along with ample bottled water
➢ Possible traffic accident in route to or from activity	➢ Use of drivers and vehicles owned and operated by Soldier On or Professional bus/ van service
➢ Contracting Covid-19	➢ We will include only individuals that have been: (A) fully vaccinated for Covid-19 and are up to date with booster. Fully vaccinated is defined by the CDC as: o 2 weeks after second dose in a 2-dose series, such as the Pfizer or Moderna vaccines, or o 2 weeks after a single-dose vaccine, such as Johnson & Johnson's Janssen vaccine *Up to date = 1 booster when eligible https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html OR o (B) Partially vaccinated against Covid-19 and willing/able to (a) complete a home antigen test for Covid-19 on the morning of each activity and report results to the PI prior to transportation departure and (b) willing to wear a mask during transportation to and from the activity. Antigen tests and masks will be provided to participants who meet this criteria. • Individuals who have been vaccinated but who have a condition or take medications that weaken their immune system will be advised to follow their physician's recommendations regarding any additional precautions.

	• We will follow all Covid-19 precautions as indicated by state and institutional policies/ guidelines as well as Soldier On policies. • Individuals who develop Covid-19 symptoms or have a positive antigen test prior to a scheduled activity will be asked to self-exclude from attending that activity, notify research assistant and to contact their health care provider. These symptoms include: Fever or chills; cough; shortness of breath or difficulty breathing; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; or diarrhea. https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html • Individuals who have been diagnosed with Covid-19 or exposed to a person with Covid-19 will be asked not to participate in activities until their isolation/ quarantine period is over.

17. POTENTIAL DIRECT BENEFITS TO SUBJECTS*

We anticipate that the activities in this study will be enjoyable to participants given data from the PIs prior studies at two of the locations. Additionally, participants may receive benefits through improvements to psychological and/or physical well-being. Moreover, we hope that the provision of the bird feeders and education might provide sustainable benefits in the future beyond study conclusion. Participants will also be provided with a journal for personal use if they would like to document future experiences observing wildlife.

18. VULNERABLE POPULATIONS*

a. No inducements, monetary or otherwise, will be offered to terminate a pregnancy
b. Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy
c. Individuals engaged in the research will have no part in determining the viability of a neonate

19. MULTI-SITE RESEARCH*
N/A

20. COMMUNITY-BASED PARTICIPATORY RESEARCH*
N/A

INVESTIGATOR STUDY PLAN - REQUIRED

21. SHARING OF RESEARCH RESULTS WITH SUBJECTS*

A presentation of the results will be provided on site at Soldier On following the conclusion of the study. Soldier On will also be provided with a copy of any publications that result from the study. Participants will have the opportunity to provide their contact information to the research team during intake if they want to be notified about results in future.

22. SETTING

We will partner with a successful veteran's organization, an internationally-renowned forest facility and three wildlife facilities that have expert staff well versed in helping the public to experience wildlife safely. Two of these (New England Wildlife Center and Maine Wildlife Park) have been sites for the PI's prior study. Letters of support have been written by all these facilities.

-Soldier On: This private non-profit organization provides housing and support services to veterans (currently approximately 600 veterans served) and UMASS Chan Medical School faculty have been partnering with them on research for the past 10 years. They have a nationally known model of sustainable affordable housing for veterans. Veterans will be recruited through Soldier On. Soldier On has multiple vehicles and drivers and has agreed to transport the veteran participants to the wildlife activity sites.[25, 26]

-Harvard Forest: This 4,000 acre forest of Harvard University was founded in 1907. The Forest is a Long-Term Ecological Research Site, funded by the NSF for research into forest dynamics. It has multiple walking/hiking trails including accessible trails. (Petersham, MA)[27]

-New England Wildlife Center: The NEWC provides veterinary care to orphaned and injured wildlife. The Center integrates care with teaching to share skills and knowledge with people of all ages. NEWC staff are experienced with integrating novices into animal care including a highly successful animal care program for inmates. (South Weymouth, MA)[28]

-Maine Wildlife Park: The MWP is a wildlife education center on 40 acres operated by the Maine Dept. of Inland Fisheries and Wildlife. The park has 100 animals (30 species) of native Maine wildlife living in a sanctuary setting. (Gray, ME)[29]

-Mass Audubon Broad Meadow Brook Conservation Center and Wildlife Sanctuary: This center is the largest urban wildlife sanctuary in New England with over 400 acres including educational facilities and a universally accessible sensory trail. (Worcester, MA)[30]

Privacy

- When recording heart rate the participants will be given a card and asked to record their heart rate by looking at their wrist monitor. Data will be written rather than spoken aloud.
- The focus groups will be held in a private room at Soldier On.
- We will schedule the interviews/ phone calls so that participants can plan in advance to be in a private space.

23. RESOURCES AVAILABLE

Describe study personnel.

Roles

INVESTIGATOR STUDY PLAN - REQUIRED

Principal Investigator
The principal investigator will manage all aspects of the study including IRB approval. This includes:

- Oversee the conduct of all facets of this study, including human subjects review, communication with team members, collaboration with community wildlife facilities, research-related activities; personal oversight of intervention activities, budget; compliance and scientific integrity;
- Be responsible for the IRB submission and overseeing human subjects procedures of all participants enrolled in the study;
- Conduct training of personnel and ensure that personnel have taken courses in Good Clinical Practice and CITI training
- Ensure that research personnel have training in all study-related procedures and standards to ensure intervention fidelity procedures are maintained.
- Meet with individuals recruited by Soldier On Research Assistant to screen for study eligibility and enroll as study participants
- Conduct baseline study measures
- Schedule intervention activities in collaboration with Soldier On and community facilities
- Refine animal-assisted activities in collaboration with Advisory Committee
- Accompany study participants during activities at community wildlife facilities
- Conduct all study measures pre and post activities
- Oversee data collection, data management and quality control with particular emphasis on data accuracy; including working with study statistician to structure the primary datasets, data linking procedures, codebook development and data documentation and security procedures.
- Perform qualitative data analysis
- Responsible for execution (along with Co-I) of the data safety monitoring plan.
- Work with the research team to prepare manuscripts, coordinate study results dissemination activities and prepare R01 for the full scale study.

- **Co-Investigator** Provide ongoing advisement to the research team as a senior scientist;
- Assist with analysis and interpretation of the data
- Serve as Safety Officer which will include reviewing monthly safety report with PI
- Consult on abstracts and manuscripts developed from the study and development of plan for future R01.

- **Co-Investigator** Design the final intervention study analysis plan in consultation with PI and other Co-I
- Be responsible for ensuring that the statistical design is implemented according to plan;
- Be responsible for the statistical integrity of the intervention study;
- Assist with execution of the data safety monitoring plan;
- Conduct, report and write up of final feasibility study analyses;
- Consult on abstracts and manuscripts developed from the study and development of statistical analysis plan for future R01.

Research Assistant (UMass Chan Medical School)
A research assistant will be hired to assist with study logistics, data collection and data entry. The research assistant will undergo CITI training and will report directly to Dr. Perry.

Community Partner (subcontract)
Soldier On is a private non-profit organization that provides housing and support services to veterans. One of the co-investigators has a strong working relationship with Soldier On from prior research. Veterans will be recruited through Soldier On for the study. Soldier On will undertake the following:

- Appoint a site advisor to serve as lead representative of Soldier On in this study Hire a research assistant to recruit participants for the study and assist with activity logistics. The research assistant will be CITI trained and listed as study staff.
- Provide transportation to study activities using Soldier On vehicles and drivers

Consultants
We will have three expert consultants, one representing each of the facility settings where animal-assisted intervention will take place. Of note is that the PI has worked extensively with two of the consultants, in her previous study.
Advisory Committee: We will convene an advisory committee to inform refinement and logistics of the intervention protocol prior to start of study, after year 1 and after study conclusion. Initial meetings will be held individually in order to focus on unique aspects of each site.

The role of the consultants is primarily to advise and assist with the study intervention rather than the research. Two of the consultants and possibly the third will likely be providing facility orientation and possibly some education for the participants as they are part of the staff at the facilities. They will not have access to identifiable research information or data. The lead person at Soldier On may have awareness of who are study participants and may be asked to assist with referrals for medical or psychiatric care if needed. This person will undergo CITI training. Other members of the advisory committee will be providing feedback on the study planning/logistics only.

24. LOCAL RECRUITMENT METHODS
Sample/ recruitment
We will recruit a total of 50 veterans with PTSD/ PTSD symptoms from Soldier On, a residential facility that currently serves 600 veterans. Recruitment flyers will be posted in residential buildings and also provided to potential candidates by Soldier On mental health clinicians and case managers. Interested individuals will be advised to contact the Soldier On research assistant who will conduct preliminary screening and schedule an initial meeting with the PI for obtaining consent and baseline data collection. During the fall/ winter period when active recruitment is not taking place any individuals who contact the research assistant regarding study participation will be assigned an ID number and will have their contact information documented in the secure research drive by the research assistant. Individuals will be told that they will be contacted for screening when enrollment resumes (anticipated approximately April 2020). The recruiter/ research assistant will be hired through a subcontract to Soldier On. Given that Soldier On is a

residential facility with two locations within 25 miles from each other, the recruiter will also identify people through their community meetings. The PI may attend some community meetings to introduce herself and describe the study. Soldier On has a specific program for women veterans and we anticipate being able to recruit a minimum of 5 women from this program.

The inclusion/exclusion criteria will be assessed via self-report. The research assistant at Soldier On will conduct screening for inclusion criteria and exclusion criteria using a designated form.

Of note, we include individuals with PTSD and subthreshold trauma (clinical symptoms without full diagnostic criteria[22]) both to increase our sample size and have a broad inclusion criteria for generalizability. Once deemed eligible, they will undergo informed consent by PI, be administered the baseline study measures and assigned to an activity group. We will recruit 30 veterans in Year I and 20 in Year II.
Our relationship with Soldier On and an on-site research assistant will also facilitate retention. Dr. Smelson (Co-I) has a long standing relationship of working with Soldier On and has obtained follow up rates above 80%. The Soldier On research assistant will contact each participant as a reminder 1 day prior to each activity. Additionally we anticipate that the wildlife activities will be enjoyable for participants. Participants will be provided with transportation and lunch. We will also provide the following remuneration for their time and to facilitate retention.

Activities 1- 7: $30 Bank of America gift card
Activity 8 (final activity): $100 Bank of America gift card
F/U interview/ phone call (20 minutes): $30 Bank of America gift card

A total of $340 will be provided for the 8 activities and follow up interview/ phone call.*

A wearable wrist fitness sensor will be provided to each participant for recording heart rate which will be given to each participant at study conclusion. Each participant will also be provided with a bird identification book during the final set of activities in order to facilitate sustainable wildlife-related activity. A certificate of attendance will be provided to participants when they complete the program as long as they attend at least 6 of the 8 activities.

*Provision of all gift cards requires that each participant's name, address and telephone number be provided to the University of Massachusetts Medical School Business Office according to institutional policy. The vendor (Bank of America) will mail the cards to participants directly. Cell phone information is already collected and stored in the R Drive for participant communication and all participants reside at Soldier On. If any individual leaves Soldier On prior to receiving their gift cards they will be requested to provide their new address. W-9, including social security number will also be collected in order to comply with UMass Chan Business Office policy. Addresses will be removed from the research records within 3 years after study conclusion. Contact information sheets will be retained for those participants who requested to be provided with study results at study conclusion.

25. LOCAL NUMBER OF SUBJECTS

50

INVESTIGATOR STUDY PLAN - REQUIRED

26. CONFIDENTIALITY

Describe the data and/or specimens.

Baseline measures collected will include:

- Demographic information: age; gender; race, ethnicity, education, branch of service; tours of deployment; medical history; substance use; medications; allergies
- Physiologic measures: heart rate; noninvasive stress markers such as heart rate are preferable as they reduce stress induced by collection[48]
- Psychological measures
    - PCL-5
    - Warwick-Edinburgh Mental-Well Being Scale (14 items)[43,44]
    - Speilberger state/trait anxiety inventory (6 items)[45]
    - Center for Epidemiologic Studies Depression (CES-D-10) scale (10 items).[46]
    - Short-form Nature-Relatedness (NR-6) (6 items) [49]
    - Human-wildlife Bridging Feelings of Valuation Scale[20]
- Animal observation journal exercise during Maine Wildlife Park visits

Pre/Post activity measures will include:

Physiological measures (heart rate before and after every activity at each site)

Psychological survey measures (after activity at each site)

Study conclusion: Focus groups and PCL-5

4-6 week F/U after final study activity: Phone/ in person interview

All scales will be completed on paper surveys, collected by the PI and stored in a locked research office.

Confidentiality: The following steps will be taken to ensure that all patient data remain confidential.

(1) *Use of numeric identifiers:* To ensure confidentiality, study assessments and electronically stored data will be identified only by a unique identifier. The master list linking the patient ID to the patient's identifying information will be maintained in a separate file and will be destroyed at the conclusion of the study. Signed consent forms will be kept in locked filing cabinets and will only be accessible to the PI and staff listed on the IRB approval.

(2) During study activities participants will be provided with a name tag for personal communication with study team and facility staff that provides their first name. If there are two individuals with the same first name in a cohort the initial of the last name will be included.

(3) *Data storage*:

Recruitment data will be entered into a UMass Chan Research Drive using an encrypted laptop maintained by the research assistant to include only name, contact information and inclusion criteria screening. This file will be destroyed at study conclusion. The screening data file will contain an ID number that will correspond to research data files but kept separately. Audio files will be securely transferred with encryption or via a UMMS IT sanctioned method, such as Move IT. Audio files will be destroyed once the transcriptions are checked for quality.

Activity data will be collected by PI in conjunction with research assistant. Post activity data will include written surveys, journal entries, and heart rate records. Data will be collected by PI and research assistants.

There will be only two journal entries per participant andthey will be conducted during the visits to the Maine Wildlife Park. This will be an exercise in which participants will be given a card/ heavy paper to write on describing their experience observing an animal of their choice. Each card will be pre-labelled with the participant's ID number. The text of the responses will be entered into a word document and the original will be destroyed after it has been entered. The PI will analyze the journal descriptions using content analysis.

Post study data will additionally include focus group recordings/ transcripts and F/U phone/in-person interview data. Participant IDs will be used with all data. No identifying information will be stored with these data or within the analytic database. All paper data collection documents will be stored in locked file cabinets within locked offices that are accessible only to the project investigators and staff. Access to the electronic data will be restricted to investigators and research staff using a designated research drive. Electronic data will be password protected to guard against unauthorized access.

(3) *Staff training*: All project staff will pass the CITI exam on ethical conduct of research. Any newly hired study staff will pass the web-based CITI exam as required by the University of Massachusetts Medical School Institutional Review Board for the Protection of Human Subjects. In addition, study staff will receive training and supervision regarding patient confidentiality. This training will be directed by Dr. Perry. The training will address the rights of patients to keep participation decision (yes or no) and all assessment data private and confidential. Training will also emphasize that discussion or disclosure of *any* information obtained from research participants during the course of the study is strictly prohibited. Prior to having any direct contact with research participants, the project assistant will receive training in recruitment and assessment procedures.

27. PROVISIONS TO PROTECT THE PRIVACY INTERESTS OF SUBJECTS
Recruitment and screening will be conducted with individual participants within a private office. For post activity data participants will be provided with a place to sit and write their answers. Responses will not be spoken. The heart rate data will be obtained by the participant writing their heart rate on a card or the the PI or research assistant looking at the wrist device and will not be spoken aloud. The focus group at the end of the study will be conducted as a group but participants will be told they only need answer questions they feel comfortable with. Post study interviews/ phone calls will be scheduled at a time during which individual can be in a private setting.

28. COMPENSATION FOR RESEARCH-RELATED INJURY
There is no compensation for research-related injury in this study.

29. ECONOMIC BURDEN TO SUBJECTS
There will be no costs to participants for this study.

30. CONSENT PROCESS
The research assistant will meet individually with potential participants to explain the study and conduct screening for inclusion criteria. The research assistant will provide a consent form at that

time for the participant to take home and read. Individuals will be then be scheduled in small groups for a second meeting at which time the PI will explain the study and obtain informed consent. Baseline demographics and measures will also be done at that time as described earlier. The PI will also meet individually with each participant to clarify any demographic questions and to allow time for any private questions. . The time between initial recruitment and the consent meeting will allow for a time period for participants to reflect on their decision. They will also be told they can stop the study at any time.
The study team will adhere to HRP-802 INVESTIGATOR GUIDANCE: Informed Consent (https://www.umassmed.edu/ccts/irb/investigator-guidance/).

31. PROCESS TO DOCUMENT CONSENT IN WRITING
Consent will be obtained in writing and will be done by the PI.
The study team will adhere to HRP-803 INVESTIGATOR GUIDANCE: Documentation of Informed Consent (https://www.umassmed.edu/ccts/irb/investigator-guidance/).

32. DRUGS OR DEVICES
N/A

INVESTIGATOR STUDY PLAN - REQUIRED

eIRB Section 7.0 Attachments Upload Checklist

Follow How to Manage Files in eIRB and upload the following items as applicable to your submission. This checklist is provided for your convenience and is not a requirement for review.

	Investigator Study Plan
	Sponsor protocol
	Research portion of the grant
	Human subjects portion of the grant
	Written approvals from ancillary reviews (Clinical Engineering, COI, IBC, PRC, RSC, Students as Subjects, etc.)
	Recruitment materials such as flyers, brochures, posters, scripts of radio ads, etc.
	Data collection sheets, case report forms, etc.
	Surveys, measures, instruments, etc.
	Measures to assess capacity to consent
	DMC or DSMB charter
	Data safety monitoring plan
	Adverse event log
	Investigator brochure or package insert for drugs
	Instructions for use or approved FDA labeling for devices
	Sponsor justification or FDA documentation for non-significant risk device study
	IND or IDE documentation
	Patient information sheet for Humanitarian Use Device
	Approval order for Humanitarian Use Device
	Product labeling for Humanitarian Use Device
	HIPAA waiver
	HIPAA authorization
	Authorization to contact form
	Consent form(s)
	Assent forms(s)
	Fact sheet(s)
	Multi-site communication plan
	Study staff training plan
	SOPs or Manuals of Operations
	Screening log
	Compensation log
	Certificates of translation or translator attestations
	Data use agreements, memoranda of understanding,
	Documentation of data/specimen anonymity (i.e., provider will never break the code)

INVESTIGATOR STUDY PLAN - REQUIRED

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