

Study Title:

Assessing mechanisms of anxiety reduction in animal-assisted interventions for  
adolescents with social anxiety

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## **BACKGROUND**

Social anxiety is a prevalent anxiety disorder that manifests as extreme fear of negative evaluation by others in social settings and avoidance of social interaction (Kashdan & Herbert, 2001). Social anxiety involves a pervasive experience of heightened anxiety and behavioral avoidance in social and performance situations with an overestimation of negative evaluation by others (i.e., negative social cues are salient or neutral cues are misinterpreted as negative) and/or a failure to appropriately process positive social feedback (i.e., positive social cues are less salient). Social anxiety disorder is the most common anxiety disorder in the United States, with a lifetime prevalence rate of 7-13% (Bogels et al., 2010; Furmark, 2002).

Unlike other anxiety disorders, social anxiety is particularly common among adolescents (5-15% lifetime prevalence; Heimberg et al., 2000; Lewinsohn et al., 1993), with average onset occurring during early to mid-adolescence (Rapee & Spence, 2004; Schneider et al., 1992). Given that the majority of social anxiety begins before the age of 18 years (Otto et al., 2001), adolescence and young adulthood is a particularly important developmental period for exploring innovative methods for intervening and preventing the negative sequelae that can result from social anxiety disorder. Social anxiety disorder in adolescence can be associated with substance abuse (Clark et al., 1996), externalizing and antisocial behavior (Davidson et al., 1993), and high rates of suicidal ideation (Francis et al., 1992), making it a critical mental health issue.

One innovative method of addressing anxiety-related conditions is the growing field of animal-assisted interventions (AAIs). AAIs incorporate animals for the purpose of meeting therapeutic goals (Jegatheesan et al., 2014). Initial evidence has demonstrated that AAIs can be effective in treating a number of mental health symptoms (Nimer & Lundhal., 2007; Souter & Miller, 2007), including anxiety (Barker & Dawson, 1998; Barker et al., 2015). Furthermore, there is evidence that contact with animals in a variety of therapeutic and non-therapeutic settings can buffer cardiovascular responses to stress (Allen et al., 1991, 2002), and social stress in particular (Polheber & Matchock, 2013).

AAIs are a particularly promising treatment option for adolescents, as engaging adolescents in traditional therapeutic treatments such as psychotherapy can be challenging, due in part, to perceived stigma (Oetzel & Scherer, 2003). The nonjudgmental nature of animals has been frequently cited as a critical component of effectiveness in various types of AAIs, providing motivation and courage to engage in a difficult activity (e.g., reading; Friesen, 2009), promoting positive social engagement (Grandin et al., 2015), providing acceptance and attention during therapy (Parish-Plass, 2008), and supporting decreased stress response (Allen et al., 2002). Furthermore, human-animal interaction has been associated with a number of positive developmental outcomes in adolescence, particularly regarding social relationships and empathic behaviors (Mueller, 2014). Given the importance of the adolescent period for social development, AAI may also be a pathway to positive outcomes in addition to promoting symptom reduction for adolescents with varying levels of social anxiety.

However, despite the promise of AAIs, several key barriers limit their use as a treatment option for social anxiety. First, the field of human-animal interaction more broadly lacks research documenting the specific mechanisms of action by which AAIs produce therapeutic outcomes. There have been repeated calls for research that addresses the specific processes driving different types of AAIs (e.g., Hoagwood et al., 2016; Kazdin, 2015). Isolating the effects of specific activities within AAIs is critical in understanding how to best design interventions for maximal therapeutic impact. For example, despite the fact that anxiety reduction has received a significant amount of attention in the AAI literature, it is still unclear exactly *how* interacting with animals can promote anxiety reduction.

Our primary goal is to test the mechanism by which AAIs reduce anxiety (**Aim 1**). There are at least two possible hypotheses for the processes underlying anxiety reduction in AAIs. First, social support is broadly associated with beneficial psychological and physiological functioning (for review, see Uchino, Cacioppo, & Kiecolt-Glaser, 1996). In particular, social support can buffer the effects of laboratory based stressors (Heinrichs et al., 2003). According to Social Baseline Theory (Coan & Sbarra, 2015), humans are inherently social, and evaluate challenges based on their ability to meet goals. Part of this implicit calculation includes social relationships (e.g. friends, family, colleagues) that might be helpful in meeting goals. One possibility is that when a person interacts with an animal, a relationship is formed that becomes part of the person's representation of social resources. For instance, being around a friendly dog might decrease the possibility of being surprised by another human or animal, thus reducing risk and decreasing anxiety. Therefore, the first mechanism we will test is whether social interaction with an animal buffers anxiety in the presence of a social stressor.

Another possible mechanism for anxiety reduction is physical touch. Since the famous "wire mother" studies by Harlow & Zimmerman (1959), researchers have explored the effects of physical touch, though the topic remains relatively understudied (Field, 2010). Most touch research has focused on interpersonal touch between two humans (for review, see Gallace & Spence, 2010). Research has found touch can reduce the experience of pain (Mancini et al., 2014) and influence heart rate, even in young children (Fairhurst et al., 2014). In a hospital setting, touch can reduce anxiety and blood pressure (though these findings are moderated by gender; Whitcher & Fisher, 1979). Less research has looked at how touching animals can influence anxiety, but initial evidence suggests that physical contact with a dog may be an important component of the interaction (Vormbrock & Grossberg, 1988; though this research has significant methodological weaknesses). Increased physical touching of a dog is correlated with less of a cortisol response in children with attachment disorders during laboratory induced stressors (Beetz et al., 2012). The second mechanism we will test is whether physically touching an animal buffers anxiety above and beyond social support alone. Initial research has suggested that contact with an animal was associated with lower anxiety than social contact with a human friend (Polheber & Matchock, 2013), suggesting that physical touch may be an important additive factor for reducing anxiety.

In addition, there is a lack of research on whether AAIs benefit adolescents with social anxiety in particular. Although existing literature supports the scientific premise that animal contact can buffer anxiety, this effect has primarily been tested in healthy adults (Allen et al., 2002; Polheber & Matchock, 2013), children with attachment disorders (Beetz et al., 2012; Wedl et al., 2015), and children with autism spectrum disorder (O'Haire et al., 2015). Our secondary goal is to specifically test the effectiveness of AAIs for adolescents with varying levels of social anxiety (**Aim 2**).

Finally, AAI research has suffered from methodological weaknesses, relying heavily on self-report measurement, non-random assignment to experimental/treatment conditions, and small sample sizes (Herzog, 2015). Although self-report measures are useful, it is critical to use multiple outcome measures for a more robust understanding of how a therapeutic strategy as complex and nuanced as AAI can be effective. The proposed study will overcome these methodological barriers by using a combination of measurement approaches, randomized experimental design, and an adequately powered study design.

Overall, the **objective** of this study is to address several key theoretical and methodological barriers in AAI research by assessing the effectiveness of different types of contact with a dog in reducing social anxiety using a robust study design with multiple measurement approaches.

## APPROACH

The primary aim of this study is to test the mechanisms by which interacting with animals reduce anxiety (**Aim 1**). The second aim is to determine if the anxiolytic effect of contact with a dog is moderated by the level of pre-existing social anxiety in adolescents (**Aim 2**). To achieve these aims, we will complete a randomized, controlled laboratory experiment that uses a powerful and well-validated social evaluative stressor, the Trier Social Stress Task for Children (TSST-C; Buske-Kirschbaum et al., 1997). To understand and measure the anxiety reducing effects of interacting with animals, we will collect three levels of outcome data: a) self-reported experience (anxiety), b) autonomic physiology (heart rate), and c) cognitive performance (error rates on mental math task).

## **Participants and Procedure**

*Eligibility Criteria:* To test the mechanism by which interacting with a dog can impact social anxiety, we will enroll 75 adolescents on a continuum of social anxiety. Given the importance of mid to late adolescence as a developmentally important period for social anxiety disorder, we will recruit adolescents ages 13-17. Individuals who are interested in participating will be screened for social anxiety using the Social Anxiety Scale for Adolescents (SAS-A; La Greca & Lopez, 1998). Parental consent and youth assent will be obtained for the screening process. The SAS-A was designed for use in adolescence and has been validated extensively across many samples and in multiple languages (e.g., Garcia-Lopez et al., 2011; La Greca & Lopez, 1998). The SAS-A contains 18 items that include three domains of social anxiety: fear of negative evaluation from peers, social avoidance and distress in new situations, and generalized social avoidance. Based on existing research suggesting the assessment of social anxiety on a continuum as compared to categories (McNeil, 2001), we will use stratified random sampling to select a balanced sample of individuals who range across low, mid, and high social anxiety (as defined by scores of  $>50$  [high anxiety] and  $<36$  [low anxiety] as recommended by La Greca, 1999). Exclusion criteria will include fear of or allergy to dogs. In total, we will enroll 75 participants (25 randomized to three conditions).

*Recruitment:* Participants will be recruited from the Massachusetts area by leveraging Tufts University resources (e.g., Tufts University School of Medicine, existing contacts through the Tufts Paws for People group, local clinics and educational programs). Parents/guardians of potential participants will be contacted via email or phone. Flyers and email announcements will be sent to relevant listserves.

*Screening procedure:* Interested participants will be provided with a link to an online screening survey. The online screener will be used to assess pre-existing level of social anxiety to inform stratified randomization, as well as exclusion criteria. Eligible participants will then be contacted with information regarding the full experimental study.

*Experimental Procedure:* During the experimental session, participants will first be informed about the study, and if consent is given by the individual (and legal parent or guardian) they will be enrolled as a participant. To test the mechanism by which interacting with dogs can reduce anxiety, participants will be randomly assigned to one of three conditions that vary the nature of the interaction: 1) interaction with a stuffed toy dog (control condition); 2) social interaction (no physical contact) with a real dog; and 3) social + physical interaction with a real dog. We will not include a physical interaction only condition because it would be impractical to block the possibility for social interaction while allowing physical interaction. A stuffed toy dog will be used as an active control condition to control for the novelty of an animal-related stimulus.

Participants in all three conditions will listen to a therapy animal handler speak for several minutes about his or her dog and view a photo of the dog, in order to further control for the novelty effects of an animal stimulus and to provide a baseline rest period (20 minutes). During this rest period, participants will also complete the first self-report anxiety questionnaire and be fitted to the wearable heart rate device.

In the control condition (1), participants will listen to the verbal presentation but there will be no animal present. Instead, there will be a stuffed toy dog (Beetz et al., 2012) and a person (to mirror the therapy dog handler). In both animal interaction conditions, one therapy dog and his or her handler will accompany the participant during all phases of the TSST-C. In the social interaction condition (2), participants will be told that the dog will be present, and they can socially interact with it at any point during the experiment (i.e., talking, social referencing), but they will not be permitted to touch the dog. In the social + physical interaction condition (3), participants will be told that the dog will be next to them and that they will be encouraged to interact socially and touch the dog during the experiment. Animal handlers are will be trained to provide consistently minimal verbal contact, to reduce the confounding effects of handler variability and distraction from the TSST-C tasks. All dog/handler teams will be approved through the Pet Partners animal therapy organization, and per the Pet Partners guidelines, all dogs will be on a 6' leash. To simulate a typical AAI environment, the handler will remain in proximity to the dog to monitor his/her behavior, but will not block the participant or interfere with the TSST-C tasks in any way.

The primary task all participants will complete is the Trier Social Stress Task for Children (TSST-C), which involves six distinct phases: baseline, anticipation, preparation, speech, mental math, and recovery (Buske-Kirschbaum et al., 1997). The TSST-C (as well as the adult version of the TSST) has been used extensively as a robust and reliable method for inducing social stress, and variants have been used in conjunction with animal interaction (e.g., Allen et al., 2002; Polheber & Matchock, 2013). The TSST-C was originally validated for use in 10-14 year olds (Buske-Kirschbaum et al., 1997), but the protocol used in this study is a specific adaptation validated for use in adolescents up to 17 years old (Stroud et al., 2009). The TSST-C involves a public speaking task and a mental arithmetic performance challenge. During the baseline rest period (20 minutes) rest period, participants will watch a science documentary (with no animal content) on a digital tablet. Participants will then be told about the task (anticipation). Then participants will have a 5-minute preparation period, and then they will be asked to speak on an academic topic for 5 minutes (e.g., give a plot summary and interpretation of a book of their choice). They will then be asked to complete a serial subtraction mental arithmetic task for 5 minutes. Per the Stroud et al. (2009) protocol, the serial subtraction task will be adjusted for age (13-14 year olds will subtract by 11s, 15-17 year olds will subtract by 17s). If an error is made, participants will be instructed to restart from the beginning.

Finally, there will be a 30-minute recovery period where they will continue to watch the science documentary. Throughout the TSST-C, participants will be asked to self-report their anxiety levels at each of the 6 phases and will wear a watch-like wristband (Empatica E4) to continuously measure heart rate data.

Compensation for the screening process will be a \$10 gift card (duration approximately 10 minutes). Youth who meet the eligibility criteria and who participate in the experiment will be compensated with a \$75 gift card (duration of the study approximately 2 hours, not including travel time to Tufts University).

## Measures

To test the mechanism of action for canine interaction in reducing social anxiety in adolescents, we will collect three levels of outcome data: a) self-reported experience (anxiety), b) autonomic physiological reactivity (heart rate), and c) cognitive performance (error rates on mental math task).

*Social anxiety.* The SAS-A will be used to assess overall level of social anxiety. The SAS-A was designed for use in adolescence and has been validated extensively across many samples and in multiple languages (e.g., Garcia-Lopez et al., 2011; La Greca & Lopez, 1998). The SAS-A contains 18 items that include three domains of social anxiety: fear of negative evaluation from peers, social avoidance and distress in new situations, and generalized social avoidance.

*Self-Report Experience:* Self-reported affective experience will be measured using the state scale of the State-Trait Anxiety Inventory (STAI; Spielberger et al., 1983), which is validated for use in adolescence and is commonly used with the TSST. The STAI state scale contains 20-items rated on a four-point scale, and has consistently demonstrated excellent reliability (ranging from  $\alpha = .86$  to  $.95$ ; Spielberger et al., 1983) and construct validity (Spielberger, 1989). Anxiety will be measured at six time points, during: (1) baseline, (2) anticipation (3) preparation, (4) speech, (5) mental math, and (6) recovery.

*Autonomic physiological reactivity:* Heart rate and electrodermal activity will be collected continuously using a clinical grade wristband sensor (Empatica E4; Garbarino et al., 2015).

*Cognitive Performance:* Cognitive performance during the social stressor task will be measured to understand how anxiety and AAI influence cognitive function. As recommended by existing research with the TSST paradigm (e.g., Simeon et al., 2007), we will measure cognitive performance during the mental arithmetic task by tracking the number of errors and lowest number reached by participants on the mental math task. Better performance will be characterized by fewer errors and reaching a lower number during serial subtraction.

*Demographic Characteristics:* In addition to the measures assessing the primary aims, we will also collect demographic covariate information from participants on age, sex, race/ethnicity, and current pet ownership.

## **PROTECTION OF HUMAN SUBJECTS**

### **1. Risks to Human Subjects**

#### **a) Human subjects involvement and characteristics**

As described in the research plan, we will recruit 75 youth ages 13-17 to participate in this study. Children will be involved in this study, given that the specific aims of the study pertain to animal-assisted interventions for adolescents with social anxiety. This age range was selected due to the importance of adolescence as a critical period for the development of social anxiety.

Participants will be recruited via stratified sampling defined by scores on the Social Anxiety for Adolescents scale (SAS-A; La Greca & Lopez, 1998). We aim to recruit 25 participants in each of three strata as defined by scores of >50 (high anxiety), 36-50 (mid anxiety), and <36 (low anxiety) as recommended by La Greca (1999). Exclusion criteria include self-reported fear of or allergy to dogs. There are no exclusion criteria based on sex or race/ethnicity.

Eligible participants will be randomized into one of three conditions: 1) control group (no contact with a therapy dog); 2) social interaction with a therapy dog (no physical contact); and 3) social + physical interaction with a therapy dog. Participants in all three conditions will complete the validated Trier Social Stress Task for Children (TSST-C), which involves a public speaking task and a mental arithmetic performance challenge. During the experiment, participants will wear a clinical grade wearable sensor (similar to a watch). They will be asked to complete a self-report questionnaire of their anxiety level at baseline (State-Trait Anxiety Inventory – State scale; STAI), during each portion of the TSST-C, and at the end of the experiment. All sessions will be video recorded.

Each potential participant will be given a \$10 gift card to complete the screening process (approximately 15 minutes, can be completed at home via digital screening tool). Youth who meet the eligibility criteria will be invited to participate in the full experiment (approximately 2 hours), and will be compensated with a \$75 gift card as an incentive for participating in the study and for travel expenses (\$50 for participation, \$25 for travel costs). This compensation rate is necessary given the specific nature of our target sample and the time investment on the part of the participants, including travel to Tufts University.

#### **b) Sources of Materials**

This project will involve four primary sources of data: (1) survey data, (2) heart rate physiology data, (3) performance data, and (4) video recording of behavior.

Prior to any data being collected, parents will be asked to read a permission form to consent to their child's participation. Children will receive an assent form before completing the eligibility screening process.

##### *1. Survey Data*

Online questionnaire data for the screening survey will be conducted through the Tufts University CTSI REDCap system, and REDCap will be used for storing all study data. REDCap allows identifier data to be flagged as sensitive, and has advanced utility for restricting access and downloading de-identified data for analysis. REDCap is HIPAA-compliant with high security (protected behind the Tufts Medical Center firewall, servers housed in a secure local data center, all web-based information encrypted). For practical reasons, it is necessary to store participant identifiers with screening data within the REDCap system. Data and identifiers will only be accessible to authorized study personnel (PI, Co-Is, and staff research assistant; not accessible to student research assistants).

In addition, participants will complete the self-report anxiety scale (STAI) during the experiment through an online survey on an iPad. The STAI survey will be administered through Qualtrics (Tufts University account), a secure, encrypted survey platform ensuring protection of data. Survey data will be password-protected through the secure platform.

The PI will randomly assign a four digit ID number to each participant (through a randomized variable creation command in Microsoft Excel). The survey data files will be downloaded onto a Tufts University secure server as an SPSS file without identifiers. All identifiers (including the key ID file) will be stored securely in REDCap.

## *2. Heart Rate Data*

Heart rate and electrodermal conductance data from the wearable heart rate monitor (Empatica E4) will be downloaded from the watch directly to a password-protected (Tufts security) Box folder. The file will be password protected and will only contain the participant's ID number (no identifying information), and will only be accessible to the PI and Co-Is.

## *3. Performance Data*

Performance during the mental arithmetic portion of the TSST-C (number of errors and lowest number reached) will be recorded securely in REDCap.

## *4. Video Data*

All sessions will be video recorded to code for social referencing behaviors between participants and the therapy animals. Video files will be downloaded immediately from the camera's USB drive (and subsequently deleted from the camera) and stored in a password-protected file on a secure Tufts University server. Two copies of each video file will be stored on the Tufts server as backup in case of file corruption, and will be retained for five years. The video data will be coded with each participant's unique four-digit ID code. Behavior coding will be quantified and stored in a password-protected NVIVO file that contains only the participants' ID numbers. The PI, co-investigators, and research assistants participating in behavior coding will be the only individuals with access to the video data. All study personnel will be CITI-certified and approved by the Tufts University Institutional Review Board.

### **c) Potential Risks**

Given the content of the questions and data collection methodologies, we anticipate minimal risk to participants. Answering questions about personal feelings and participating in the social stressor situation as part of the Trier Social Stress Task may have risk of causing emotional distress, particularly for participants who are experiencing high levels of social anxiety. The TSST-C has been well-validated for use in youth populations (Buske-Kirschbaum et al., 1997; Stroud et al., 2009) and has been widely used without causing undue risk to participants. For participants who are randomized to the conditions that involve interacting with a dog, there is always minor risk associated with interacting with live animals.

## **2. Adequacy of Protection Against Risks**

### **a) Recruitment and Informed Consent**

Participants will be recruited from the Massachusetts area by leveraging advertisement through Tufts University resources (e.g., Tufts University School of Medicine, existing contacts through the Tufts Paws for People group, local clinics and educational programs). Flyers and email announcements will be sent to relevant listserves.

Consent for completing the brief online screening tool will be obtained digitally. Upon clicking on screening survey link, parent will be asked to complete a permission form for their child's participation. After parental consent/permission is received, the survey will direct to an assent form that youth will be asked to read and respond to. If youth agree to participate in the screening survey, they will then be directed to the survey.

For participants who are eligible to participate in the experiment, parental consent and youth assent will be obtained in person. A CITI-certified researcher will explain the nature of the study, and the risks, and parents/guardians will be asked to respond to a hard copy consent form. If the parent consents, then the youth participant will be asked to read and respond to a similar assent form. All participants and their parent/guardian will be reminded that they can choose to not participate in the study without any consequences, and that they may discontinue at any time once the study has begun.

### **b) Protection Against Risks**

As noted above, there are minimal risks associated with this study. Although risks are minimal, we will provide participants with the PI's contact information should any questions or concerns arise, as well as provide contact information for mental health resources. We will also highlight the participant's right to discontinue his or her participation in any part of the study (including the TSST-C) at any time. If a participant becomes distressed during the TSST-C, the study will be stopped immediately, and the participant and his or her parent/guardian will be provided with contact information for a mental health professional.

As noted above, confidentiality of digital data will be maintained by assigning a four digit ID number to each participant that will be stored securely in REDCap. De-identified data files and video data files will be stored on a secure Tufts University server and will only be accessible by the PI and the co-investigators.

The animals participating in this study will be therapy dogs who are registered through Pet Partners® and members of Tufts Paws for People, reducing the risk of adverse events. The animals will always be accompanied by their handlers, who are required by Pet Partners to have their dogs on leash at all times while visiting and have been trained to advocate for their animals to ensure safety of all participants. As part of their Pet Partners training, all animal handlers have completed an 8-hr training course and their animals have passed a rigorous evaluation (with re-evaluation every 2 years) to meet training, safety, and health standards that protect both the animal-handler team and the people and facilities they are visiting. The animals are bathed 24 hours prior to participating in any program, and the teams are covered by comprehensive liability insurance through Pet Partners.

### **3. Potential Benefits of the Proposed Research to Human Subjects**

There are no direct benefits to participants other than helping researchers better understand how contact with therapy animals may reduce anxiety for adolescents.

### **4. Importance of the Knowledge to be Gained**

The results of this research will provide important data exploring the mechanisms of action underpinning anxiety reduction in animal-assisted interventions (AAI). The proposed study will expand our knowledge about both if and how AAI can be an effective strategy for reducing social anxiety. Using novel and rigorous methods to address a fundamental question in AAI, this study represents theoretical, methodological, and translational innovations in AAI research. Overall, this award would allow us to better understand the processes involved in effective AAI. Given the potential benefits for understanding and promoting the potential positive impact AAI on anxiety, the benefits of this study outweigh the minor risks.

### **5. Data Safety and Monitoring Plan**

**Safety Monitoring:** Given the content of the questions and data collection methodologies, we anticipate minimal risk to participants. Answering questions about personal feelings and participating in the social stressor situation as part of the Trier Social Stress Task may have risk of causing emotional distress, particularly for participants who are experiencing high levels of social anxiety. The TSST-C has been well-validated for use in youth populations and has been widely used without causing undue risk to participants. For participants who are randomized to the conditions that involve interacting with a dog, there is always minor risk associated with interacting with live animals.

Although risks are minimal, we will provide participants with the PI's contact information should any questions or concerns arise, as well as provide contact information for mental health resources. We will also highlight the participant's right to discontinue his or her participation in any part of the study (including the TSST-C) at any time. If a participant becomes distressed during the TSST-C, the study will be stopped immediately, and the participant and his or her parent/guardian will be provided with contact information for a mental health professional. If any minor skin irritation or discomfort takes place as a result of wearing the E4 wristband, it will be removed immediately.

The animals participating in this study will be therapy dogs who are registered through Pet Partners® and members of Tufts Paws for People, reducing the risk of adverse events. The animals will always be accompanied by their handlers, who are required by Pet Partners to have their dogs on leash at all times while visiting and have been trained to advocate for their animals to ensure safety of all participants. The animal handlers are trained to recognize stress signals in their dogs and will discontinue participation immediately if the therapy animal becomes stressed.

**Reporting Adverse Events:** Though adverse events are not anticipated, if a participant becomes distressed during the study will be stopped immediately, and the participant and his or her parent/guardian will be provided with contact information for a mental health professional. If any animal handler or study personnel notice stress signals in the animal subjects, the animals will be removed. In addition, any adverse events will be reported immediately to the Tufts University Institutional Review Board and/or Institutional Animal Care and Use Committee as dictated by their reporting guidelines, and to the NIH. Adverse event reporting will remain the responsibility of the primary investigator, though any

staff or participants will be asked to contact the primary investigator with any questions, concerns, or suspected adverse events.

**Data Protection:** All data will be stored securely using the Tufts University CTSI REDCap system, which is HIPAA-compliant with high security (protected behind the Tufts Medical Center firewall, servers housed in a secure local data center, all web-based information encrypted). The PI will randomly assign a four digit ID number to each participant, and the key ID variable will be protected in REDCap. Questionnaire/survey data will be administered through Qualtrics (Tufts University account), a secure, encrypted survey platform ensuring protection of data. Survey data will be password-protected through the both of these platforms, and identifiable data will be restricted. The survey data files will be downloaded onto a Tufts University secure server as a data file. Physiology data from the wearable sensor will be downloaded as a data file. The file will be password protected and will only contain the participant's ID number (no identifying information).

All sessions will be video recorded to code for social referencing behaviors between participants and the therapy animals. Video files will be downloaded immediately from the camera's USB drive (and subsequently deleted from the camera) and stored in a password-protected file on a secure Tufts University server. Two copies of each video file will be stored on the Tufts server as backup in case of file corruption, and will be retained for five years. The video data will be coded with each participant's unique four-digit ID code. Behavior coding will be quantified and stored in a password-protected Excel file that contains only the participants' ID numbers. The PI, co-investigators, and research assistants participating in behavior coding will be the only individuals with access to the video data.

**Trial Monitoring:** Participant safety and data monitoring procedures will be approved by the Tufts University Institutional Review Board. The PI will directly monitor that all Tufts University IRB approved protocols for maintaining confidentiality are followed and that participant safety is maintained. All research personnel will be CITI-certified.