I. TITLE AND ABSTRACT

<u>Evaluating the Effects of Service Dogs on Children with Autism Spectrum Disorder (ASD) and Their Caregivers</u>

Rationale: ASD is a chronic developmental disorder that impacts 1 in 55 children in the US[1]. Although there is no cure for ASD, many treatments are effective in improving communication and behavior[2]. One complementary treatment increasingly pursued by families of children with ASD is a specially trained autism service dog[3]. However, despite anecdotal and preliminary accounts of their efficacy[4-9], there remains a *<u>critical need</u>* for empirical evaluation of the effects of service dogs for children with ASD on clinically-meaningful outcomes. Further, there is a need for research on the effects of these service dogs on caregivers of children with ASD, who often face significant caregiving burden and stress[10]. The *<u>objective</u>* of the proposed study is to fill these research gaps by empirically evaluating the effects of service dogs on children with ASD and their caregivers. *<u>This research is relevant to HABRI</u>* because it assesses an increasingly prevalent but inadequately researched application of the human-animal bond for a growing and at-risk population. Findings from this project will be used as preliminary data towards a randomized controlled trial (NIH R01) with longitudinal evaluation of targeted outcomes.

Hypothesis/Objectives: An innovative approach will combine standardized self- and proxy-report with objective physiology to quantify outcomes for both children with ASD and their caregivers with and without a service dog in the home. We *<u>hypothesize</u>* benefits in three aspects of service dogs' efficacy, evaluated in the following objectives:
➤ *Objective 1*: Assess differences in <u>ASD symptomology</u> in children with ASD, including social and interfering behaviors, via standardized caregiver-report (Social Skills Improvement System[11], Aberrant Behavior Checklist[12]).
➤ *Objective 2:* Assess differences in <u>stress physiology and sleep</u> in children with ASD via a salivary biomarker of stress (cortisol awakening response[13]) and standardized caregiver-report (Children's Sleep Habit Questionnaire[14]).
➤ *Objective 3:* Assess differences in <u>caregiver and family wellbeing</u> via standardized caregiver-report (Questionnaire on Resources and Stress[15], Pediatric Quality of Life Inventory Family Impact[16], Pittsburgh Sleep Quality Index[17]).

Study Design and Methods: Using a cross-sectional design we will compare outcome measures between populations of children with ASD ages 5-12 and their caregivers with and without a service dog. We will compare 50 families engaging in usual care that have an ASD service dog (*treatment group*) to 50 families engaging in usual care while on the waitlist to receive a service dog (*control group*). Sample size is based on a power analysis using a small effect size (d=0.40, power=0.80, α=0.05). Families will be recruited from one of the largest service dog providers in the US, Canine Companions for Independence (CCI), with whom we have already developed a partnership.

Preliminary Data: A retrospective survey was conducted with 48 families with an ASD service dog from CCI. Survey results as well as a thematic analysis of anecdotal quotes suggested several perceived benefits of the service dog for the child, including increased social interactions, better communication skills, and less problem behaviors in public (Obj. 1) as well as less anxiety, reduced arousal, and better sleep habits (Obj. 2). Among caregivers, results suggested increased quality of life including reduced stress, improved sleep quality, and better family functioning (Obj. 3). Although promising, these findings are limited by substantial recall and/or reporting biases, the lack of a control group, and measurement lacking in clinically-valid, standardized methodology or physiological assessment.

Expected Results: Among children with ASD, we anticipate that having a service dog in the home will be associated with lower ASD symptomology including better social skills and fewer problem behaviors (Obj. 1) as well as lower morning cortisol and better sleep quality (Obj. 2). Among caregivers, we expect that having a service dog will be associated with decreased caregiving stress, less health-related family impact, and better sleep quality (Obj. 3).

Budget and Timeline: The proposed project will be completed within 2 years for a total cost of $85,493 (Year 1 = $37,014, Year 2 = $40,707; includes 10% indirect costs of $7,772).

Potential Impact for Human-Animal Bond: As the largest and most extensive study on service dogs for children with ASD and their caregivers to date, findings will provide critically-needed outcomes for this increasingly prevalent application of the human-animal bond. Knowledge gained will help identify target endpoints for a future NIH R01 randomized controlled trial that is essential to legitimize and establish a sufficient evidence base for this practice. Ultimately, this research has the potential to validate theorized impacts of the human-animal bond on the fastest-growing developmental disability in the US while improving the lives of both children of ASD and their families.

II. RESUBMISSION SUMMARY

N/A

III. TITLE PAGE

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IV. ORGANIZATION NAME AND ADDRESS

Purdue University
College of Veterinary Medicine
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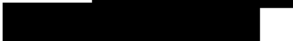## V. OFFICER AUTHORIZED TO SIGN AGREEMENTS

Amanda Hamaker, CRA, CPRA
Director, Pre-award, Purdue University
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VI. STUDY PROPOSAL

I. Specific, Testable Hypotheses and Objectives

Our *long-term research goal* is to evaluate and enhance the applicability of the human-animal bond as a complementary treatment for improving the wellbeing of special populations including children with ASD and their families. The *specific goal of this project* is to quantify the therapeutic effects of service dogs on children with ASD and their caregivers. To achieve this goal, we will pursue the following testable hypotheses and objectives:

➢ Objective 1: Assess the effect of a service dog on **child ASD symptomology**, including social and interfering behaviors, via standardized caregiver-report. We *hypothesize* that children with a service dog will have less severe ASD symptomology, including significantly higher social and communicative skills and less frequent interfering/problem behaviors, than matched waitlist controls.

➢ Objective 2: Assess the effect of a service dog on **child stress physiology and sleep** via a salivary biomarker of stress and caregiver-report. We *hypothesize* that children with a service dog will have lower physiological arousal indexed by a lower cortisol awakening response as well as better sleep quality and bedtime habits than matched waitlist controls.

➢ Objective 3: Assess the effect of a service dog on **caregiver and family wellbeing,** including caregiver burden, caregiver health-related quality of life, caregiver sleep quality, and overall family functioning via caregiver-report. *We hypothesize* that caregivers with a service dog will report less caregiving stress, better quality of life, and better sleep quality as well as higher overall family functioning than caregivers of matched waitlist controls.

II. Justification, Significance, and Literature Review

ASD is a chronic and pervasive disorder that impacts up to 1 in 55 children in US[1]. As ASD diagnoses continue to rise, so does the demand for effective treatments. Although there is no known cure for ASD, caregivers of children with ASD will often engage in several home and school-based treatment regimens to improve the child's social skills, communication, and behavior[18]. In addition to evidence-based treatments, 74% of families will engage in complementary treatments to address the child's needs[19]. One increasingly prevalent complementary treatment is animal-assisted intervention (AAI) in the form of a specially trained autism service dog[3]. Preliminary research[4-9] suggests that the service dog's trained tasks and companionship may reduce children's ASD symptomology and physiological arousal while decreasing caregiver burden and worry. However, current literature on ASD service dogs is largely limited by anecdotal reports[5-7] and the use of measures that are not clinically validated[9]. Further, two systematic reviews of the literature on AAI for ASD by PI O'Haire suggest promising findings in the field but an overall severe lack of methodologically rigorous research[20,21]. There remains a *critical need* to empirically quantify the effects of ASD service dogs not only on clinically-relevant outcomes for children with ASD, but also on caregiver and family functioning[10]. Our *rationale* for this research is that without established efficacy, this potentially promising application of the human-animal bond for an at-risk population will remain largely unsubstantiated and unsupported by the broader scientific and clinical community[22]. The proposed study attempts to fill this research gap by quantifying the efficacy of ASD service dogs based on the following scientific premises:

Outcome Domain	Scientific Premise	Measurement
Objective #1: Effect of service dogs on CHILD ASD SYMPTOMOLOGY		
Social communication & interaction	Dog motivates social engagement, acts as a social bridge with peers and strangers, and encourages communication[23-25]	SSIS[11]
Interfering/problem behaviors	Dog acts as a multisensory stimulus to maintain positive attentional focus[26 27], reduces negative arousal and decreases problem behavior[4,9]	ABC[12]
Objective #2: Effect of service dogs on CHILD STRESS PHYSIOLOGY AND SLEEP		
Stress response	Dog reduces negative arousal[9] and provides stress buffer[28 29]	Salivary CAR[13]
Sleep difficulties	Dog instills sense of routine, provides deep pressure and comfort at night[4,6]	CSHQ[14]
Objective #3: Effect of service dogs on CAREGIVER & FAMILY WELLBEING		
Health-related quality of life	Dog improves family functioning[6 7 30 31] and decreases caregiver worry[4 32 33]	PedsQL[16]
Caregiving stress	Dog relieves caregiver burden and reduces stress[4 8 31 33]	QRS-F[15]
Sleep difficulties	Dog promotes a sense of safety and reduces caregiver worry at night[4,8]	PSQI[17]

This research is **significant** in several ways. First, it _addresses a fundamental gap_ in current treatment options for ASD. As ASD diagnoses continue to increase, so too have the therapeutic modalities to address the spectrum of etiologies and symptoms of ASD. Caregivers of children with ASD must navigate an overwhelming and continuously evolving array of treatment options[18]. Many complementary and alternative treatments, including service dogs, may be popular among the ASD community but lack a scientific evidence base[2]. Qualitative reports suggest that a service dog may be an effective complementary treatment that addresses the needs of the entire family unit[4,6,7]. However, until this practice is empirically assessed for its efficacy, families deciding whether to undertake this long-term commitment will not know what to expect or if a service dog will be appropriate for their needs. This research thereby attempts to overcome a _critical barrier to progress in the field_ by evaluating a commonly pursued but poorly studied complementary treatment option for children with ASD and their caregivers[22]. Additionally, this research is significant as it employs a family-wide approach to quantify the effects of a service dog on the child, the caregiver, and family functioning. Caregivers of children with ASD exhibit more stress, depression, and lower health-related quality of life than caregivers of children with other physical or mental disabilities[34]. Additionally, research has shown that the negative behavioral aspects of ASD represent a significant stressor not only to the child and caregiver but to the larger family system as a whole[35]. Therefore, this research addresses an important problem for children with ASD and their families who represent an underserved[36] and rapidly growing population[37] in the US.

In addition to its significance, this research is also **innovative**. First, it uses a combination of standardized self-report, proxy-report, and objective measurements with a large, representative sample. It employs objective methodology (salivary cortisol) to elucidate the potential mechanisms through which a service dog may attenuate stress and influence arousal, which has only been explored in one existing study to date[9]. Successful completion of this study will thus provide a much-needed evidence base for this unique application of the human-animal bond as well as a foundation in which to focus on future optimal allocation and implementation of this practice. Second, this project is innovative as it evaluates the effects of service dogs on caregivers to offer insight into how this complementary treatment option can potentially offer family-wide benefits beyond the child. ASD service dogs differ from the traditional service dog model in that the dog is handled by and receives commands from the primary caregiver but is trained to serve the needs of the child. This unique triad presents an unparalleled opportunity to quantify both the direct and indirect effects of a service dog on children with ASD, their caregivers, and the family unit.

III. Preliminary Data

A preliminary survey was conducted with N=48 caregivers of children with ASD who had previously received an ASD service dog from Canine Companions for Independence (CCI). Caregivers were asked to retrospectively reflect on life before and after obtaining a service dog. Survey results and anecdotal quotes (analyzed via a thematic analysis) were then used to determine the objectives in the proposed study. This preliminary data, together with a successful history of collaboration between the research team and CCI, demonstrate the _feasibility_ of the proposed work.

Objective 1: Child ASD Symptomology. When asked how the recipient's life has changed since receiving a service dog, 92% of caregivers reported increased social interactions with both peers as well as strangers in public. In anecdotal quotes of the service dog's effects, 46% of caregivers mentioned improvements to the child's social communication skills. Finally, 50% of families reported that their child had fewer behavioral difficulties at their school/day program after the introduction of a service dog while 31% of families reported no change in this domain.

Objective 2: Child Stress Physiology & Sleep. Since receiving a service dog, 92% of caregivers reported improvements in the child's peace of mind while 73% of caregivers reported an improvement in the child's sleep. Further, 29% of quotes on the service dog's efficacy specifically mentioned the dog's ability to provide a calming presence and relieve anxiety in the child.

Objective 3: Caregiver & Family Wellbeing. Almost all (94%) of caregivers reported that since receiving a service dog, the family's peace of mind has improved. Further, 68% of caregivers reported improvements to the family's sleep while 81% of caregivers also reported an increase in the number of family trips to public places.

Although promising, findings from this preliminary survey are limited by their retrospective nature, subjecting participants to significant recall and/or reporting biases. Furthermore, there is no control condition to account for the

effects of time and treatment as usual. Finally, questions were not from validated, standardized surveys which can offer clinically-relevant interpretation of findings.

IV. Experimental Methods and Design

Research Team & Roles. Our interdisciplinary research team possesses the skills necessary to successfully carry out the proposed project. Specifically, our team has expertise in assessing animal-assisted intervention for children with ASD (PI O'Haire), the physiological mechanisms of child-canine interaction including salivary cortisol (Co-PI MacLean), and biopsychosocial and behavioral measurement among children with ASD (Co-PIs Tonnsen, Rispoli). In addition, with project management by graduate researcher Rodriguez, PI O'Haire's research group has already successfully conducted three national, cross-sectional studies on the effects of service dogs for recipients and families in varying populations, collecting over 1,000 surveys and 2,000 salivary cortisol samples to date. PI O'Haire's prior HABRI-funded research laid the foundation for a successful NIH R21 clinical trial. The proposed project will combine PI O'Haire's prior research protocols in this context with her prior experience working with children with ASD for a planned trajectory of HABRI funding as pilot data towards an R01 clinical trial.

Design. We will use a cross-sectional design to measure the effects that a service dog (in combination with standard care) may have on children with ASD ages 5-12 and their caregivers. Specifically, we will compare matched families engaging in usual care that either have a service dog in the home (*treatment group*) or are on the waitlist to receive a service dog (*control group*). We will recruit from the database of one of the largest accredited service dog providers in the US, Canine Companions for Independence (CCI).

Theoretical framework. This study's objectives and design are based on the two key underlying theories of the human-animal bond: social support theory, in which the animal acts as a non-judgmental source of support and a catalyst for social interaction[38-40], and the biophilia hypothesis[41], in which the animal acts as a positive external focus of attention to reduce anxious arousal[42,43].

Participants. Eligible families will include those who have been screened and accepted by the service dog provider (CCI). The *treatment group* will consist of families who have been previously placed with an autism service dog for a minimum of 6 months, while the *control group* will consist of families who are awaiting future placement. Inclusion criteria for child participants will include: (a) 5-12 years old, (b) an existing ASD diagnosis on record with the service dog provider (Autistic disorder, Asperger syndrome, pervasive developmental disorder (PDD), or pervasive developmental disorder-not otherwise specified (PDD-NOS) from a medical, psychological, or educational professional), (c) no co-occurring genetic conditions (e.g., Retts, Fragile X), and (d) exceeds diagnostic cutoff on the Autism Symptom Inventory[44]. To maximize sample size, child participants will not be excluded from participation based on their intellectual capacity or engagement with other treatments. Inclusion criteria for caregivers will consist of (a) over 21 years old, and (b) self-identifies as either a parent or caregiver living in the same home as the child.

Service dogs. All service dogs provided by CCI are purpose-bred Golden Retrievers, Labrador Retrievers, or Golden-Lab hybrids. ASD service dogs are trained for over 30 commands, including ASD-specific tasks such as interrupting self-stimulatory behavior at the direction of the caregiver or providing calming deep pressure by laying on or next to the child. CCI provides service dogs free of charge to recipients.

Recruitment and feasibility. Based on a power analysis using a conservative effect size[45] (d=0.40, power=0.80, α=0.05), we will compare n=50 families in the treatment group to n=50 families in the control group (total of N=100 families). Based upon our previous similar research[46,47] and similar studies[48,49] we expect a roughly 50% response rate. Therefore, we will need to recruit at least N=200 families to participate, including n=100 with a service dog and n=100 on the waitlist. The CCI database includes nearly 400 families previously placed with an ASD service dog as well as a multi-year waitlist. This sample size has been successfully recruited by our research group[46,47].

Participant recruitment will occur on a rolling basis by first recruiting families on the waitlist to receive a service dog and subsequently matching consenting waitlist participants to families already placed with a service dog. Matching will be based on the child's age and sex as well as the families' socioeconomic status. By collecting data for both waitlist and service dog groups at the same time, the confound of time of participation will be reduced. This rolling design will also maximize research personnel time for attentive participant communication.

Procedure. Eligible families will be initially recruited with a mailed study flyer, a description of participation, and relevant consent forms. Families will then be called by research personnel to explain the study, establish participant-researcher rapport, and obtain voluntary informed consent from the primary caregiver. Participation will include caregivers completing a 20-minute diagnostic phone assessment for the child, filling out a 30-minute online survey, and facilitating three mornings of saliva collection with the child.

Compliance and Retention. To encourage compliance for the survey, we will use an online survey software[50] with a user-friendly design, the ability to complete the survey across multiple platforms, and automated reminders. To encourage compliance for saliva collection, user-friendly and aesthetically pleasing instructions and videos will be created to maximize protocol adherence (PI O'Haire has successfully used these protocols in a previous study to collect over 600 saliva samples[51]). Families will also be compensated $60 for participating in the research including $20 for competing the online survey and $40 for completing three days of saliva collection.

Measures. Children's ASD diagnoses will be verified and assessed via a remote diagnostic assessment called the *Autism Symptom Interview* (ASI)[44]. The ASI is a validated phone assessment designed for researchers to confirm and quantify an ASD diagnosis in large-scale studies in which face-to-face diagnostic interviews are not feasible[44]. The ASI is based off a gold-standard, multi-hour diagnostic interview[52], but can instead be administered over the phone in roughly 20 minutes. Phone assessments will be completed by a trained member of the research team who will be masked to participants' treatment group to minimize unintentional biases during assessments.

Caregivers will also fill out an online 30-minute survey. This survey will contain a brief demographic section quantifying child-specific variables (child age, sex, co-occuring conditions, current ASD treatments, current medication use) and caregiver-specific variables (caregiver age, sex, employment, education, household income, size of family). The survey will also measure psychosocial outcomes with a series of standardized measures.

<u>Child ASD Symptomology (Objective 1):</u> The *Social Skills Improvement System Rating Scales* (SSIS-RS)[11] is a 79-item proxy-report standardized behavior rating scale for children with ASD. The SSIS-RS is split into two scales which measure social skills and problem behaviors. The *Aberrant Behavior Checklist* (ABC)[53] is a 58-item proxy-report of disrupting/problem behaviors including five subscales: irritability, social withdrawal, stereotypic behavior, hyperactive/noncompliance, and inappropriate speech. Both the SSIS-RS and ABC have high validity, high reliability, and are sensitive to animal-assisted intervention[54,55] and pet dog ownership[25] among children with ASD.

<u>Child Stress Physiology and Sleep (Objective 2):</u> Caregiver-facilitated saliva collection will quantify the *cortisol awakening response (CAR)*[13] among children with ASD, a commonly used psychophysiological biomarker of both chronic and acute stress[56] that quantifies the increase in the stress hormone cortisol after awakening. To capture the CAR, three saliva samples will be taken across three weekdays (0, 30, and 45 minutes after awakening[57]) for a total of nine samples per child. Home sampling protocols will be replicated from previous studies with children with ASD[58] which include the use of child-friendly oral swabs and sugar-free gum to stimulate saliva flow[59]. Compliance will be facilitated with color-coded, user-friendly sampling kits and an automated SMS text messaging system to track sample times[57]. As an additional measure of control, caregivers will also fill out a brief questionnaire for each sample taken regarding the relative difficulty of obtaining the sample and their perceived rating of the child's stress. Caregivers will overnight their samples to Purdue University to be stored in a secure -80°C freezer before batch assay at the Interdisciplinary Institute for Salivary Bioscience Research (IISBR). Samples will be assayed for cortisol using a commercially available enzyme immunoassay (Salimetrics, Carlsbad, CA) with a 25μl test volume and lower limit sensitivity of 0.007 g/dL. To capture child sleep, the *Children's Sleep Habit Questionnaire* (CSHQ)[14] is will be used. The CSHQ is a 45-item proxy-report of a child's behaviors surrounding sleeping, and one of the most widely used measures to assess sleep in children with ASD. The measure has eight subscales: bedtime resistance, sleep onset delay, sleep duration, sleep anxiety, night wakings, parasomnias, sleep-disordered breathing, and daytime sleepiness.

<u>Caregiver and Family Wellbeing (Objective 3).</u> The *Pediatric Quality of Life (PedsQL) Family Impact Module*[16] is a 36-item measure of the impact of a child's health condition on the quality of life and family functioning of a primary caregiver. The module has four domains: health-related quality of life, family functioning, communication, and worry. The *Questionnaire on Resources and Stress Short Form* (QRS-F)[15] measures caregiving stress and beliefs regarding a child's health. The 31-item short form contains two subscales: parent and family problems and pessimism. The *Pittsburgh Sleep Quality Index* (PSQI)[17] is a 19-item measure of sleep quality and disturbances. The PSQI captures seven subscales: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep

disturbances, use of sleep medication, and daytime dysfunction. The PedsQL, QRS-F, and PSQI all exhibit high reliability and validity and have been widely used among caregivers of children with special needs.

Statistical analyses. To examine the effect of having a service dog on psychosocial outcomes, data will be analyzed using a series of hierarchical multiple linear regression models with two sets of independent variables. The first set will include all demographic and medical covariates appropriate for either child or caregiver outcomes, while the second set will include the primary predictor of interest, having a service dog or being on the waitlist. Potential covariates for both children and caregivers will consist of age, sex, family income, and presence of a pet dog in the home. Child-specific covariates will additionally include the presence of developmental, psychiatric, or neurologic co-occurring conditions. Caregiver-specific covariates will include employment, education, and number of children. Covariates will be preliminary examined for differences across group (using t-tests for continuous variables and chi-squared tests for categorical variables) and included in subsequent models when appropriate to account for key confounding variables while conserving statistical power. To examine the effect of having a service dog on physiological outcomes, CAR will be analyzed using a mixed model with a within-subject random effect for sampling day and a between-subject fixed effect of having a service dog. Additional fixed effects will include relevant state and trait covariates recommended by expert guidelines for CAR analysis[57] (age, sex, body mass index, co-occurring conditions, medications that may influence cortisol, baseline salivary cortisol at awakening, and time of awakening).

Expected Outcomes. Expected outcomes include a description of cross-sectional differences among those with and without a service dog in the home for both children with ASD and their caregivers. Specifically, this study will provide critical outcome data on both psychosocial and physiological effects of service dogs on children with ASD. Further, this study will describe the effects of an ASD service dog on caregiving stress, health-related quality of life, and sleep quality among caregivers of children with ASD. In addition to providing initial evidence of the therapeutic efficacy of service dogs for children with ASD and their caregivers, findings will determine the feasibility and projected effect sizes for a more resource-intensive longitudinal clinical trial (NIH R01). First, physiological data will assist in elucidating the potential mechanisms in which a service dog may attenuate stress and influence arousal among children with ASD. Second, survey data will inform the choice of targeted longitudinal outcomes that may be the most sensitive to change following the provision of a service dog.

Potential Problems and Alternative Strategies. A first potential problem of this research may be difficulty in saliva collection among children with ASD. Specifically, some children may be reluctant to cooperate or experience discomfort with the oral swab. There is also a chance that sampling difficulty may cause a stress response among children that could translate into higher observed cortisol. However, two strategies will be used to minimize this problem. First, we will stress to caregivers the importance of aborting saliva collection if significant child distress is observed. Second, we will implement a difficulty and perceived distress rating for each sample (see *Measures* section). If we do find a positive correlation between sample difficulty/distress and cortisol values, we will control for this statistically. A second potential problem may be lower than expected participation. Caregivers of children with ASD are a sensitive and burdened population who may be hesitant to participate in time-consuming study activities. To maximize participation, we will establish strong rapport with participants, develop user-friendly and aesthetically pleasing instructions, and remain sensitive and respectful to participants' time and needs. Strategies will also be implemented in both saliva collection and online surveys to maximize completion (see *Compliance and Retention* section). Finally, our interdisciplinary research team has extensive experience in conducting successful remote research with sensitive populations including caregivers of children with special needs[32,47,60,61] and military veterans with PTSD[46,51].

V. Timeline

Study Timeline	YEAR 1												YEAR 2											
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12
Obtain institutional approval	■	■																						
Prepare protocols & materials			■	■	■																			
Recruitment & data collection						■	■	■	■	■	■	■	■	■	■	■	■							
Salivary cortisol assay																		■	■					
Data analysis & dissemination																				■	■	■	■	■

VII. HUMAN/ANIMAL SUBJECTS JUSTIFICATION AND REGULATORY INFORMATION

All procedures will be submitted to the Purdue Institutional Review Board (IRB) for review and approval prior to data collection. As no interactions will occur between the research team and service dogs and all data collected will be from human participants only, a waiver will be obtained from the Purdue Animal Care and Use Committee (PACUC).

VIII. FACILITIES AND EQUIPMENT

Purdue University, Center for the Human-Animal Bond (PI O'Haire, Graduate Student Rodriguez)

Established in 1982, The Center for the Human-Animal Bond (CHAB) lies within the College of Veterinary Medicine at Purdue University. A major objective of CHAB is to foster interdisciplinary research by serving as a focal point for the exchange of ideas and development of new information related to animal-human interactions.

Within the Center for the Human-Animal Bond, PI O'Haire has a dedicated laboratory space that is specifically focused on human-animal interaction research. Approximately 500 square feet of space is equipped with 7 computing workstations. The computers have password-protected access to a private service space for large-scale and secure data storage. Further, six telephones with three separate phone lines allow efficient participant communication due to the ability to hold and transfer calls, track caller identification and missed calls, and record voicemail messages. To conduct sensitive phone calls, a smaller dedicated and private calling space has been designated in the building for PI O'Haire's use. The PI has licenses for MatLab for physiological data processing and the Statistical Package for the Social Science (SPSS) for data analysis. Within the building, the laboratory hosts a -80C freezer that is secure and only accessible by keycard and a secure passcode. This freezer contains dedicated space the storage of salivary samples. Finally, the College of Veterinary Medicine has a variety of expert support personnel, including secretarial services, purchasing, and accounts agents. An administrative office at the building entrance triages the arrival of all mail, which will include overnight frozen samples of salivary assays from participants. Administrative personnel are trained in the receipt and immediate freezer allocation of these samples.

Arizona University, Arizona Canine Cognition Center (Co-PI Maclean)

The Arizona Canine Cognition Center (ACCC) was formed in 2017 within the School of Anthropology in the University of Arizona. Approximately 840 square feet of lab space contains multiple computing stations that can be used for scoring videos, data entry, and analysis as well as space for project meetings. Students and post-docs have working space, new desktop computers, and equipment for coding, analyzing and long-term storage of data. The ACCC maintain a 24TB mirrored secure server for the management of all study data. In addition, our lab has access to UA High Performance Computing resources for computationally or memory intensive computing tasks.

Purdue University, Purdue Autism Cluster (Co-PIs Rispoli & Tonnsen)

The Purdue Autism Cluster (PAC) is a consortium of faculty engaged in interdisciplinary and highly coordinated research efforts for understanding, assessing, and treating individuals with autism spectrum disorders. PAC also engages a large network of researchers, community members and providers of autism related services. Co-PI Rispoli acts as the co-director of the PAC and leads a productive research group focused on assessment and treatment of challenging behavior in young children with ASD or other developmental disabilities. Co-PI Tonnsen is a member of the cluster and leads a large research group studying children with neurodevelopmental disorders.

Canine Companions for Independence (CCI):

Founded in 1975, Canine Companions for Independence (CCI) is a non-profit organization that breeds, trains, and places assistance dogs to assist individuals with physical, cognitive and developmental disabilities. CCI has six regions throughout the United States including their headquarters in Santa Rosa, CA. At each location CCI houses 50-100 dogs at any given time and maintains dedicated kennels and breeding areas for their populations of Labrador and Golden Retrievers and crosses of the two breeds. CCI maintains state-of-the-art veterinary facilities and employs a full-time veterinary staff to ensure the health and wellbeing of all animals at this site.

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X. BUDGET				

Category	Year 1	Year 2	Year 3	Total
Personnel:				
1. Principal Investigator (O'Haire)	$0	$0		
2. Co-investigator #2 (Maclean)	$0	$0		
3. Co-investigator #3 (Rispoli)	$0	$0		
4. Co-investigator #3 (Tonnsen)	$0	$0		
5. Graduate Student (Rodriguez)				
Graduate Student Salary (50%)	$20,754	$20,754		
Fringe benefits (7.5%)	$1,557	$1,557		
Total Salary & Wages:	$22,311	$22,311		
Supplies & Expenses:				
1. Cortisol collection kits	$2,458	$0		
2. Shipping fees for samples	$2,150	$1,200		
3. Cortisol assay	$0	$13,856		
4. Participant compensation	$6,000	$0		
5. Questionnaire instruments	$755	$0		
6. Graduate student fee remissions	$3,340	$3,340		
Total Supplies & Expenses:	$14,703	$18,396		
Animal Use & Care:				
Animal Purchase: N/A				
Animal Per diem: N/A				
Total Animal Care: N/A				
Subtotal of All Categories:	$37,014	$40,707		
Maximum of 10% - Indirect Costs: **	$3,701	$4,071		
Grand Total Requested from HABRI:	**$40,715**	**$44,778**	**$85,493**	N/A

* Salary requests for principal investigators must be clearly defined and justified in the following budget justification section. You may request salary for technicians, residents, graduate students, and postdoctoral fellows, based on their percentage of time involved in the project. Postdoctoral fellows who are applying as a PI are welcome to apply for salary support up to 50% of their full-time appointment.

** Indirect costs may be claimed only if you are charged for indirect costs by your institution for work carried out in this proposal. **You must make this calculation yourself.** If your institution charges less than 10%, claim only that amount and indicate the percentage.

XI. ITEMIZED BUDGET JUSTIFICATION

Personnel

1. Principal Investigator (PI) Dr. Marguerite O'Haire will be responsible for all oversight of the project including design, implementation, and interpretation of study results. She will coordinate the interdisciplinary team, with whom she has already established strong working relationships. She will manage the project and provide hands-on assistance to graduate assistant Rodriguez. She will also be the primary point of contact for collaboration with the service dog provider. *No salary compensation for PI O'Haire's effort is requested.*

2. Co-PI Dr. Evan Maclean will advise on the design, implementation, and interpretation of results with regards to service dog behavior and mechanisms of human-animal interaction. He has years of expertise interpreting cortisol data and will be instrumental in interpreting physiological findings. In addition, with more than 5 years working with CCI, Dr. Maclean will serve as a point of contact with the service dog provider. *No salary compensation for Co-PI Maclean's effort is requested.*

3. Co-PI Dr. Mandy Rispoli will advise on the design and interpretation of results, especially in regards to child participant problem behavior and social behavior data. With a wealth of research knowledge and experience regarding children with ASD and their caregivers, Dr. Rispoli will serve as a valuable consultant in this research. *No salary compensation for Co-PI Rispoli's effort is requested.*

4. Co-PI Dr. Bridgette Tonnsen will advise on the design and interpretation of results, especially in regards to child participant ASI diagnoses, co-occurring conditions, and the complexities surrounding individual differences in children and families. *No salary compensation for Co-PI Tonnsen's effort is requested.*

5. Graduate Assistant Kerri Rodriguez will be responsible for the hands-on running of the project. Responsibilities will include: preparation of study materials including saliva collection instructions and videos, managing online surveys, participant recruitment and communication, and database organization. Ms. Rodriguez will also be responsible for data analysis and subsequent manuscript preparation following completion of the project. *Salary compensation for Rodriguez's effort is requested at $20,754/year.*

Supplies and Expenses

1. Cortisol collection kits. Supplies for salivary cortisol home collection include 2mL color-coded cryovials, oral child swabs, and biohazard bags for shipping. In the laboratory, salivary cortisol expenses include cryovial storage boxes, gloves, and maintenance of a -80 freezer ($2,458).

2. Shipping fees. Funds are requested for postage to send recruitment envelopes to participants nationwide which will include information about the study and saliva collection supplies. Return postage will be included for participants to overnight saliva samples back to Purdue upon collection. Overnight shipping will also be required to send salivary samples for batch assay at the end of the study ($3,350).

3. Cortisol assay. Saliva samples will be batch assayed in duplicate for cortisol at the Institute for Interdisciplinary Salivary Bioscience Research (IISBR) at a rate of $12.83 per sample ($13,856).

4. Participant compensation. Funds are requested to provide each family with a financial compensation of $20 for completing the survey portion of the study and $40 for completing three mornings of saliva collection ($6,000).

5. Questionnaire instruments. Funds are requested to purchase licenses to use standardized, validated survey instruments to assess ASD symptomology including the SSIS-RS ($407, Pearson) and the ABC ($348, Slosson; Total of $755).

6. Graduate student fee remissions. Funds for graduate student fee remission are required for all graduate student research assistants at a rate of $7,740 per year. However, internal competitive funds will assist with a portion of these costs (total requested $3,340/year).