UNIVERSITY OF CALIFORNIA, IRVINE
CONSENT TO ACT AS A HUMAN RESEARCH SUBJECT

Animal Assisted Intervention with Dogs for Children with Attention Deficit/Hyperactivity Disorder; Exploring Candidate Physiological Markers of Response to AAI

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STUDY LOCATION(S):
The Children's School
3400 Michelson Drive, Suite #200
Irvine, CA
92612

STUDY SPONSOR(S):
Eunice Kennedy Shriver National Institute of Child Health & Human Development

In the instance of parental permission, "You" refers to "Your child."

SUMMARY OF KEY INFORMATION:

The information provided in this box includes a brief yet complete summary of key information about the research, presented first as required by the federal regulations. Some sections that require additional information may be repeated later in this document.

Participation is Voluntary
You are being asked to participate in a research study. Participation is completely voluntary. Please read the information below and ask questions about anything that you do not understand. A researcher listed above will be available to answer your questions.

Study Purpose
The purpose of this research study is to replicate previous findings that social-behavioral outcomes are improved for children with ADHD when they participate in an 8to10 week Animal Assisted Intervention (AAI) with therapy dogs and to explore if candidate physiological markers are improved over time for children with ADHD in response to this intervention. Additionally, we seek to explore if potential individual differences in children with ADHD effect the way children respond to AAI. Examples of these potential differences may include the variability in heart rate and variability while interacting with therapy dogs and/or in the frequency with which children touch or therapy dogs during AAI sessions.

Study Procedures
Your child will be randomly assigned to an intervention group upon consent. Intervention sessions will include 6-8 children who attend 8 weekly AAI sessions (120 min) with 3 certified therapy dog/handle dyads,1 moderator and 2 behavior counselors or 8-10 weekly SST sessions which follow the same treatment protocol but do not included therapy dog/handler dyads. After screening for eligibility, consent, and group assignment, you and your child will attend an assessment session on the Saturday prior to (1), immediately following (2), and 8 weeks post intervention (3). You and your child will be given verbal and written instructions about collecting saliva samples and you will be provided with a home saliva collection

kit for providing six (6) total samples prior to participants attending the first assessment session and this procedures will be repeated at the conclusion of the intervention and then again 8 weeks later. You will be required to place saliva samples on a provided cold-pack and cooler until picked up from your home by study staff for delivery to our lab . All samples will be de- identified using barcodes. Saliva samples will also be collected from your child at three of the 8 intervention sessions and heart-rate will also be measured during those sessions using a wearable electronic device placed on your child's chest upon arrival.

Expected Duration

To determine study eligibility, you and your child will participate in one (1) Parent & Child screening visit that is expected to last approximately **2-3 hours**.

Participation over the course of the study will last approximately 16-18 weeks and will require:

- On a total of six (6) days across the course of the study (16-18 weeks), you will collect three (3) saliva samples from your child at home for two (2) days in a row (a Thursday and Friday), collecting six (6) total samples prior to each of the Saturday assessment days (before, after, and 8 weeks post intervention (a total of 18 samples per child). Each sample takes approximately 2-3 minutes to swab and seal (less than one (1) hour total over the course of study).
- On a total of three (3) Saturday assessments (immediately before, after, and 8weeks post intervention) you will be required to participate in assessment for a total of approximately two (2) hours for each session (6 total hours over 16-18 weeks) and your child will be required to participate in assessment for a total of approximately six (6) hours for each session (18 total hours over 16-18 weeks).
- Your child will participate in a total of eight-ten (8-10) weekly intervention sessions that will last approximately 120 minutes each (approximately 16-20 hours total over 8-10 weeks).

Risks of Participation

The greatest potential risk for children interacting with dogs include the danger of an animal bite or that a dog might carry diseases with potential transmission to humans. Though these are potential dangers, risks of interacting with participating therapy dogs are minimized by a strict safety screening protocol including a review of animal health, history, certification by reputable therapy animal certification organizations, and dog/handler interview. This safety protocol was developed in a prior study by the Lead Investigator which included eight-one children and over a dozen therapy animals over the course of 4 years and resulted in zero incidents of injury or disease transmission (Schuck, Emmerson, Abdullah, Stehli, Fine, & Lakes, 2018). Also, should there be a breach in confidentiality of your data, there is a slight risk that your private information could be shared with individuals who are not members of the study team.

Benefits to Participants

The possible benefits your child may experience from the procedures described in this study include improved social skills including improved self-esteem and pro-social behavior and reduced symptoms of inattention and oppositional behavior.

Benefits to Others or Society

The possible benefits to science and society include providing information about how potential biological responses to animals may enhance treatments for children with ADHD. This information is important as there are few evidence-based non-pharmacological interventions for this group of individuals who remain at risk for poor life outcomes despite the effectiveness of medicines for the symptoms of ADHD.

Clinical Trial Registration

This study is a clinical trial examining non-biomedical interventions for ADHD, sponsored by the *Eunice*

Kennedy Shriver National Institute for Child Health & Human Development at the National Institutes of Health. As such, this study will be registered with *ClinicalTrials.gov* within 21 days of the first participant being enrolled.

A description of this clinical trial will be available on https://www.clinicaltrials.gov/, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Alternative Procedures or Treatments
The known alternative procedures for decreasing the symptoms of ADHD include treatment with medicines that have been found to decrease symptoms (e.g., Dexedrine®, CONCERTA®, Focalin®, Adderall®, Adderall® XR, Ritalin®, Ritalin LA®, etc.). The known alternative procedures for improving social skills for children with ADHD include social skills training alone, behavior modification treatments (applied behavioral analysis) and behavioral parent training.

Compensation
Families will be compensated for their participation in each of the three (3) Saturday assessment sessions attended, $60 at the conclusion of each session for a total of $180.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY? This study will enroll approximately 52 participants over the course of two years. Assessments and interventions will occur at The Children's School in Irvine, California. Saliva collected from children by parents will occur at your home. Analysis of de-identified saliva samples will occur at the laboratory of one of our collaborating study team members. .

AM I ELIGIBLE TO PARTICIPATE IN THIS STUDY?
You and your child must meet the following requirements to be in the study:

- *Your child will be aged 7 to 9 years by the first assessment session*
- *Your child meets research diagnostic criteria for ADHD*
- *Your child does not meet research diagnostic criteria for Major Depression, Bi-polar Disorder, Intellectual Deficit.*
- *Your child does not have a history of cruelty to animals.*
- *Your child speaks and understands English*
- *You are fluent in English*

WHAT PROCEDURES ARE INVOLVED WITH THIS STUDY AND HOW LONG WILL THEY TAKE?

1) **Screening for Eligibility & Intervention Group Assignment**
   - Upon consent, you and your child will participate in a screening interview to determine if you are eligible for participation in the study. This interview will take approximately **2-3 hours**.
   - After consent and eligibility has been determined, your child will be randomly assigned to and intervention group that will **begin within approximately 5 weeks of when you were found to be eligible.**

2) **Assessment & Saturday Lab School**
   - After consent, screening for eligibility, and group assignment, you and your child will attend a total of three Laboratory School Assessment on the Saturday prior to (1st), immediately following (2nd), and 8 weeks post intervention (3rd). Recess times on these Laboratory School days will be video recorded.

3) Intervention Sessions

- On a weekday (tbd) in the week following the 1st Lab School, your child will attend the first of eight to ten (8-10) Intervention sessions which will include 6-8 children who attend each of the 8-10 weekly after school social skills training sessions for (approximately 120 min) led by one moderator 1 moderator and 2 behavior counselors and *either with or without the assistance of 3 certified therapy dog/handle* dyads. Both groups will follow the same treatment protocol but only one will included therapy dog/handler dyads. These sessions will be video recorded.

4) Saliva samples and Heart Rate

- You and your child will be given verbal and written instructions about collecting saliva samples and you will be provided with a home saliva collection kit for providing six (6) total samples prior to participants attending the first Lab School Assessment session and this procedures will be repeated at the conclusion of the last Lab School Assessment session and then again 8 weeks later.
- You will be required to place saliva samples on a provided cold-pack and cooler and return then to the study staff for delivery to our lab. All samples will be de- identified using barcodes.
- Saliva samples will also be collected from your child during three of the 8-10 intervention sessions by study staff trained to obtain and handle these samples.
- Your child's heart-rate during Lab School Assessment sessions and during Intervention sessions will be measured by wearing a small device which we will instruct you how to place on your child's chest in private upon arrival and remove at dismissal in private prior to leaving.

Total Participation time in the study will include about 16-10 hours of intervention, and about 15-20 hours of assessment, (including approximately 1 hour total of home sample collection), over a period of approximately 2-3 months, depending on when you are enrolled and when the first Lab School Assessment session is held and parents will participate in approximately 9-10 hours of assessment.

RETURN OF RESULTS

You will not receive individual research results. If the final findings of this research are found to be clinically relevant to your child's future health treatment decisions, research results, including general or aggregate research findings will be available at the time results are deposited to National Clinical Trials Repository.

WHAT ARE THE POSSIBLE DISCOMFORTS OR RISKS RELATED TO THE STUDY?

There are no known harms or discomforts associated with this study beyond those encountered in normal daily life for children interacting with trained dogs. The possible risks and/or discomforts associated with the procedures described in this study may include:

- Physical: Minimal likelihood of a dog bite and minimal likelihood of transmission of disease from dog to human
- Psychological: Embarrassment or anxiety associated with answering questions about your behavior and/or feelings
- Privacy: Potential breach of confidentiality.

WILL I BE PAID FOR TAKING PART IN THIS STUDY?

Compensation

Families will be compensated for their participation in each of the three (3) Saturday Lab School Assessments assessment sessions attended, $60 at the conclusion of each session for a total of $180.

If you decide to withdraw from the study or are withdrawn by the research team, you will receive compensation for the Saturday Lab School Assessments that you have completed.

Compensation will be provided to subjects in the form of a check issued to you through the UCI Accounting Office. Your name, address, and social security number, will be released to the UCI Accounting Office for the purpose of payment and for tax reporting to the Internal Revenue Service (IRS) in the case in which you have received greater than $600 for your participation in studies at UC over a period of a year.

Reimbursement
You will not be reimbursed for any out of pocket expenses, such as transportation fees. Parking is free at the site.

Costs
There is no cost to you for participation in this study. However there may be out-of-pocket expenses such as parking and transportation fees.

WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?
It is important that you promptly tell the researchers if you believe that you have been injured because of taking part in this study. You can tell the researcher in person or call him/her at the number listed at the top of this form.

If you are injured as a result of being in this study, UCI will provide necessary medical treatment. The costs of the treatment may be covered by the University of California or the study sponsor, the *Eunice Kennedy Shriver Institute* for Child Health and Human Development, or billed to you or your insurer just like other medical costs, depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For more information about this, you may call the UCI Human Research Protections unit at (949) 824-6662 or by e-mail at IRB@research.uci.edu

WHAT HAPPENS IF I WANT TO STOP TAKING PART IN THIS STUDY?
You are free to withdraw from this study at any time. **If you decide to withdraw from this study you should notify the research team immediately**. The research team may also end your participation in this study if you do not follow instructions, miss scheduled visits, or if your safety and welfare are at risk.

If you withdraw or are removed from the study, the researcher may ask you to *return for a final visit or evaluation or complete an exit telephone interview.*

If you elect to withdraw or are withdrawn from this research study, you may choose to terminate the continued use or disclosure of your protected health information (PHI) for research purposes. The request to end the use or disclosure of your PHI should be made in writing.

You are free to withdraw your consent to use your identifiable private information and biospecimen for future research at any time however there are some limitations. If you withdraw your consent, the researchers will not use your information or biospecimens in future research studies. However, any of your information or biospecimens already being used in a research study that began before your request to withdraw will continue to be used for that specific study. Also if information and biospecimens have already been provided to another researcher, institution, or company, it may not be possible to limit their continued and new uses.

HOW WILL MY PERSONAL INFORMATION BE KEPT?
Subject Identifiable Data

Identifiable information collected about you will be removed and replaced with a code. A list linking the code and your identifiable information will be kept separate from the research data. Personal identifiers will only be retained for the purpose of recruitment, scheduling, and for providing compensation.

Audio/visual recordings will not be de-identified prior to analysis and as such, parents or a legal authorized representation must provide explicit permissions for the study team to collect photographs and/or audio/video recordings. This explicit permission must include the specific purposes for which this identifiable information will be sued (i.e., structured, observation of behavior, training, presentation). Please see the included Release Form required for this research procedure.

Data Storage

Research data will be maintained in paper format in a secure location at UCI. Hard copy data will be stored in a locked cabinet in the private office of the LR in Medical Sci., Bldg. C. and not accessible to non-study team members.

Research data will be stored electronically on a secure network in an encrypted file with password protection only available to the research team.

The audio/video recordings that can identify you will also be stored in a secure location and then immediately downloaded to a secure server within 24 hours of recording and deleted from the portable device and then permanently erased from the server as soon as analysis is complete; and for no more than two years past the study's completion.

Biospecimens will be stored in a locked lab/refrigerator/freezer at the laboratory that will perform the analysis of de-identified specimens, under the supervision of one of the study team members and willnot be accessible to non-study team members.

Only de-identified data will be shared with non-UCI-collaborating investigators.

Data Retention

In accordance with UC Office of the President policy, information/biospecimens will be retained for 10 years after the end of the calendar year in which the research is completed, unless otherwise specified in the award agreement.

WHO WILL HAVE ACCESS TO MY STUDY DATA?

The research team, authorized UCI personnel, authorized NICHD personnel, and regulatory entities such as the Office of Human Research Protections (OHRP), may have access to your study records to protect your safety and welfare.

While the research team will make every effort to keep your personal information confidential, it is possible that an unauthorized person might see it. We cannot guarantee total privacy.

Future Research Use

Researchers will use your *specimens and* information to conduct this study. Once the study is done using your *specimens and* information, we will not share them with other researchers outside of the study team. We will not share your name or any other private identifiable information that would let the researchers know who you are. We will not ask you for additional permission to share this de-identified information.

Certificate of Confidentiality

To help us protect your privacy, we are in the process of obtaining a Certificate of Confidentiality from the National Institutes of Health (NIH). With this Certificate, researchers cannot be forced to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings or be used as evidence, for example, if there is a court subpoena, unless you have

consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by NICHD which is funding this project. You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law. Researchers will voluntarily disclose information to prevent serious harm to you or to someone else including, *the conditions under which voluntary disclosure would be made may include but may not be limited to child abuse, elder abuse, domestic violence or sexual assault, animal abuse.*

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document such research data about your child's medical history included in your oral interview.

ARE THERE OTHER ISSUES TO CONSIDER IN DECIDING WHETHER TO PARTICIPATE IN THIS STUDY?

Investigator Financial Conflict of Interest
One of the Consultants of this study, who will have no engagement with the study participants, holds a financial interest in one of the companies which produces and sells some of the saliva receptacle units used for our planned collection of saliva samples.

Use of Biospecimens
Biospecimens (such as blood, tissue, or saliva) obtained for routine labs will be discarded or destroyed once they have been used for the purposes described in this consent.

Future Contact
The study team would like your permission to contact you for future research. Please initial your level of permission below:

_____ Yes, UCI researchers may contact me in the future to ask me to take part in other research studies.

_____ No, UCI researchers may **not** contact me in the future to ask me to take part in other research studies.

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?
If you have any comments, concerns, or questions regarding the conduct of this research, please contact the research team listed at the top of this form.

You may take up to one hour at the time of this consent to make your decision about your participation.

Please contact UCI Institutional Review Board by phone, (949) 824-6662, by e-mail at IRB@research.uci.edu or at 160 Aldrich Hall, Irvine, CA 92697, if you are unable to reach the researchers listed at the top of the form and have general questions; have concerns or complaints about the research; have questions about your rights as a research subject; or have general comments or suggestions.

What is an IRB? An Institutional Review Board (IRB) is a committee made up of scientists and non-scientists. The IRB's role is to protect the rights and welfare of human subjects involved in research. The IRB also assures that the research complies with applicable regulations, laws, and institutional policies.

HOW DO I AGREE TO PARTICIPATE IN THIS STUDY?
You should not sign this consent form until all of your questions about this study have been answered by a member of the research team listed at the top of this form. You will be given a copy of this signed and dated consent form to keep. **Participation in this study is voluntary.** You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your future relationship with UCI or your quality of care at the UCI Medical Center.

_____ Yes, I agree to allow the research team to video record my child during the Laboratory School Assessment Sessions
_____ No, I do not agree to allow the research team to video record my child during the Laboratory School Assessment Sessions

_____ Yes, I agree to allow the research team to video record my child during the Intervention Sessions
_____ No, I do not agree to allow the research team to video record my child during the Intervention Sessions

Your signature below indicates you have read the information in this consent form and have had a chance to ask any questions you have about this study.

I agree to participate in the study.

_____ _____
Subject Signature **Date**

_____
Printed Name of Subject

_____ _____
Legally Authorized Representative/Guardian Signature ***Date***

_____ _____
Printed Name of Legally Authorized Representative/Guardian ***Relationship to Subject***

_____ _____
Legally Authorized Representative/Guardian Signature ***Date***

_____ _____
Printed Name of Legally Authorized Representative/Guardian ***Relationship to Subject***

_____ _____
Signature of Person Obtaining Informed Consent **Date**
(For research that is greater than minimal risk, this individual must be listed on Page 1 of this consent)

_____
Printed Name of Person Obtaining Informed Consent