



Consent to Participate in Research

Study Title: Oxytocin Pathways and the Health Effects of Human-Animal Interaction

Principal Investigator: Evan MacLean

Sponsor: National Institute of Child Health and Human Development

Summary of the research

This is a consent form for participation in a research study. Your and your child's participation in this research study is voluntary. It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to ask questions before making your decision whether or not to participate.

This is a study about the effects of dog-child interaction. Your child will participate in a series of activities including social interactions with your pet dog and with an unfamiliar dog, and play with toys. You and your child will complete questionnaires about the child's typical interactions with your dog. We will collect saliva and urine samples for hormonal and genetic analyses. The study requires three 90-minute research visits, across a period of three weeks. There is no direct benefit to you.

Why is this study being done?

This study is being performed to evaluate the biological, behavioural, and psychological effects of social interaction between children and dogs. We are investigating how dog-child interaction affects three hormones, called oxytocin, vasopressin, and cortisol. Oxytocin and vasopressin are hormones that are involved with social behaviour, and which affect our responses to stress. Cortisol is a hormone that also responds to stress. We aim to understand how dog-child interaction affects these hormone concentrations, and whether this may contribute to possible health benefits of pet ownership.

What will happen if I take part in this study?

The study involves 3 visits to the Arizona Canine Cognition Center (ACCC) during which your child will have social interactions with your pet dog and with an unfamiliar dog, and play with a variety of toys. This activity will be monitored on a live video feed by experimenters and parents to ensure the safety of participants, and video recordings will be stored in a secure location for later analysis. We will collect saliva samples from your child before, during, and after these activities. We will also collect a urine sample from your child before and after these activities.

The genetic measurement will assess one gene that affects how the hormone oxytocin functions. A Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. Be aware that this Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

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In addition, your child will provide answers to questions from two questionnaires about his or her feelings about pets, and you will complete one questionnaire about your child's typical interactions with your dog. To participate, you will be required to visit the Arizona Canine Cognition Center three times, each visit lasting approximately 90 minutes. Below is a brief description of what these sessions will entail:

Pet dog: Upon arrival at the Arizona Canine Cognition Center (ACCC), your dog will be taken to a nearby room, accompanied by an experimenter, and you and your child will rest in the ACCC lobby for 15 minutes. This lobby is furnished with a TV and children's books that will be available during this time. After 15 minutes, the child will provide saliva and urine samples, immediately after which the child will be taken to the adjacent experiment room and reunited with the dog. For the next 25 minutes, your child will be allowed to interact freely with the dog on a padded floor mat (an assortment of dog toys will be provided to facilitate dog-child interaction). Fifteen minutes into this interaction, an experimenter will enter the room to assist with collection of a second saliva sample from both the child and dog, after which interaction will resume for another 10 minutes. After this period, children will return to the lobby where they will be allowed to rest for 20 minutes prior to collection of the final urine and saliva samples.

Unfamiliar dog: The unfamiliar dog condition will be identical to the pet dog condition, with the exception of the following: Your child will interact with a 7-year old female Labrador retriever from the breeding colony of Canine Companions for Independence (CCI), the largest non-profit provider of assistance dogs in the United States. This dog, 'Sisu', has a friendly temperament, seeks and enjoys interactions with unfamiliar humans, and is gentle but engaging with children.

Toys: The procedure for the control condition will be identical to the conditions above with the exception that in lieu of interacting with a dog, the child will be provided age-appropriate toys (e.g. Magna-Tiles®, kinetic sand, coloring materials, construction sets, and arts and crafts materials).

How long will I be in this study?

You and your child will participate in three research visits, scheduled across 3 weeks.

How many people will take part in this study?

80 participants: 40 children, and their parents, will take part in this study.

What benefits can I expect from being in this study?

There is no intended clinical benefit to you or your child for participating.

What risks or benefits can I expect from being in the study?

The risks of participation in this study are minimal. There is a risk of injury if your child is bitten or scratched by a dog. To limit this risk, your child will interact with a dog that was bred and trained for friendly interactions with children, and who has no history of aggression. There are minimal risks of psychological distress if participants are upset by reflecting on the state of their relationship with, or routine care for, their pet dog. It is also possible that some children will experience mild stress when visiting the University for data collection.



You or your child may benefit from knowing 1) that you are participating in a study that seeks to explore whether, and to what extent, social relationships with dogs affect human health, and 2) that these data may be used to expand human-animal interaction programs to improve the lives of other families in the future. Results from the study could also potentially improve the ways in which dogs are viewed and treated in society and increase adoption rates of homeless dogs across the country.

What other choices do I have if I do not take part in this study?

Your and your child's participation is voluntary. If you or your child decide to take part in the study, you or your child may leave the study at any time. No matter what decision you or your child make, there will be no penalty to you or your child and you or your child will not lose any of your usual benefits. Your and your child's decision will not affect your future relationship with The University of Arizona. If you are a student or employee at the University of Arizona, your decision will not affect your grades or employment status.

When may participation in the study be stopped?

Your and your child's participation is voluntary and you or your child may choose to leave the study at any time. Researchers may withdraw your child from the study if a dog behaves aggressively toward your child and we feel that your child is at risk of being harmed.

What are the costs of taking part in this study?

You will be responsible for your own transportation to the University of Arizona and you will be required to devote approximately 90 minutes of your time for each study visit.

Will I be paid for taking part in this study?

You will be paid a total of \$150 for your participation. You will receive \$40 for completing the first visit, \$50 for completing the second visit, and \$60 for completing the third visit. At each visit, your child will receive a small toy, with an approximately \$10 value. If you decide to participate in the study, you will be provided free parking.

Will my data or specimens be stored for future research?

The identifiable information or biospecimens collected will not be used or distributed for future research without first seeking your consent.

To help us protect your privacy, the researchers have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you. The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency-funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

Will my specimens be sold for commercial profits?

Specimens will not be sold for commercial profits.

**Will I hear back on any results that directly impact me?**

You or your child will not receive any clinically relevant results discovered about you and/or the general subject population.

Will my study-related information be shared, disclosed, and kept confidential?

Your or your child's name will not be used in any report. Identifiable research data will be encrypted and password protected. Your and your child's responses will be assigned a code number. The list connecting your and your child's name to this code will be kept in an encrypted and password protected file. Only the research team will have access to the file. When the study is completed and the data have been analyzed, the list will be destroyed.

Who can answer my questions about this study?

If at any time you feel you or your child have had a research-related injury, or for questions, concerns, or complaints about the study you may contact **Dr. Evan MacLean** by email (evanmaclean@email.arizona.edu) or by phone (520-621-0386).

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Human Subjects Protection Program at 520-626-6721 or online at <http://rgw.arizona.edu/compliance/human-subjects-protection-program>.

A description of this clinical trial will be available on <http://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.

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**Signing the consent form**

I have read (or someone has read to me) this form, and I am aware that my child and I are being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to have my child and I participate in this study. I am not giving up any legal rights for my child or myself by signing this form. I will be given a signed copy of this form.

Printed name of subject

Signature of subject

Date

Printed name of person authorized to consent for subject (when applicable)

Signature of person authorized to consent for subject (when applicable)

Date

Relationship to the subject

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