

**Consent Form: The development and evaluation of a novel Cat Assisted Training (CAT) intervention for youth with developmental disabilities and their family cat.**

NCT05950672

September 13, 2023



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### CONSENT FORM

**Project Title:** The development and evaluation of a novel Cat Assisted Training (CAT) intervention for youth with developmental disabilities and their family cat

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**Sponsor:** National Institutes of Health (NIH)

**Version Date:** September 29, 2022

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### SUMMARY

We are inviting you and your child to take part in a research study. You and your child do not have to be in the study if you do not want to. You and your child can also decide to be in the study now and change your mind later.

This study is about the benefits of an animal-assisted training intervention for children with developmental disabilities, using the family cat.

If you and your child take part in this study, we will ask you and your child to complete questionnaires and for your child and the family cat to take part in a program over the course of 6 sessions (about 45 minutes for each session).

The most serious risks related to being in this study are scratches and bruises like those a child might obtain from participating in regular physical activities.

The main benefit of being in this study is that your child may improve their physical activity behavior.

We plan to make the results of this study public.

We would like you to ask us questions if there is anything about the study that you do not understand. You can call us at (541) 737-3273 or email [megan.macdonald@oregonstate.edu](mailto:megan.macdonald@oregonstate.edu).

You can also contact the Human Research Protection Program with any concerns that you have about your rights or welfare as a study participant. This office can be reached at (541) 737-8008 or by email at [IRB@oregonstate.edu](mailto:IRB@oregonstate.edu).

There are more details about the study in the following pages.

**1. WHAT IS THE PURPOSE OF THIS FORM?**

This form contains information you and your child will need to help you decide whether to be in this research study or not. Please read the form carefully and ask the study team member(s) questions about anything that is not clear.

**2. WHY IS THIS RESEARCH STUDY BEING DONE?**

The purpose of this research study is to develop and evaluate a Cat Assisted Training intervention (CAT) focused on youth (8-17 years old) with developmental disabilities and their family cat.

Up to 30 children with developmental disabilities and their parent/guardian may be invited to take part in this study—this means a total of 60 participants (30 children and up to 30 parents/guardians).

**3. WHY AM I BEING INVITED TO TAKE PART IN THIS STUDY?**

You and your child are being invited to take part in this study because you have a child who is 8-17 years old with a developmental disability. In addition, you have a family cat that is at least two months old and will also participate in this study.

**4. WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH STUDY?**

You will fill out questionnaires and verbally answer questions about you and your child. Your child will take part in a number of assessments that have been adapted from other measures used with children. The first assessment will determine your child's ability to follow instructions. Your child will participate in a game similar to "Simon Says". Your child must successfully complete this assessment to move on to the other parts of this research study.

Your child will take part in a number of assessments that have been adapted from other measures used with children. Assessments your child will participate in include questions about their emotions as well as their relationship with and attachment to their pet cat. You will also participate in several behavior tests along with your family cat. All of these assessments will take place at three different time points throughout the study, at the beginning, about 6 weeks later, and about 1 year later.

After the baseline assessments, you, your child, and your family cat will go through a process called randomization.

**Randomization** means that you are put into one of the groups by chance. It is like drawing names from a hat. Neither you nor the people doing the study will choose what group you will be in. Your child will be placed either in the CAT Intervention Group or the Control Group.

The CAT intervention group will take part in the training program directly after baseline testing. Children in the CAT intervention group will participate in a 6 session cat training program, similar to an after-school program. Each session lasts approximately 45 min. There will be 3 assessments per child over a period of about one year. During CAT, all CAT training methods will be positive-reinforcement based, using owner-approved treats, toys, and/or social engagement where appropriate. Children will learn about cat body language, behavior, and proper cat handling techniques. Children will be assigned "homework" to continue training and learning more about their cat's behavior while at home.

Participants in the Control Group will complete the same assessments as the intervention group. However, the Control group will not receive an intervention immediately. Those children in this group will not participate in the cat training program during the initial study period but will be offered the opportunity to participate in the cat training program following their completion of their third assessment [e.g., after about 1 year]).

In instances where your child's behavior indicates to the researcher potential signs of stress or emotions that might indicate their unwillingness to participate, the research team will contact you. This conversation will be to discuss your child's behavior and the best plan of action for your child. For example, this might include your child's voluntary withdrawal from the study, your child's voluntary withdrawal from an activity (e.g., assessment or other activity) within the study, or your child's need for a break (e.g., snack, bathroom break, play break, etc.).

As indicated in the consent form you will sign for your cat's participation in this study, there may be instances where the cat's participation is terminated by the investigator (e.g., cats experiencing more than minor distress that cannot be immediately mitigated or cats evidencing signs of fear, aggression, etc.).

Study duration: We expect that you and your child will be enrolled in this study for about 12-16 months.

Our study team will continuously comply with State and University regulations regarding COVID-19 exposure.

**Recordings and photographs:** Video and audio recordings will be taken in parts of this study. This is a required part of the study. If you do not wish for this video recording to take place, you and your child should not take part in this study. Please initial where applicable:

I **AGREE** for my child and I to be video and/or audio recorded. \_\_\_\_\_  
Initials

I **DO NOT AGREE** for my child and I to be video and/or audio recorded. \_\_\_\_\_  
Initials

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**Continue to next page**

### **Optional video & photography**

The research team hopes to have the opportunity to present the findings from this study at conferences and through other media publications. With your permission, we may use some of your information in these presentations. Photographs will include anonymized images, thus your name and/or your child's name will not be included in presentations/media publications. Videos may include identifiers (e.g., your child could call your cat by name), thus it is possible that direct (e.g., child's name) or indirect (e.g., cat's name) identifiers might be used.

**I agree**, on behalf of myself and my child, to be video recorded and photographed for the purpose of presentations and media publications of this research (please initial where applicable):

\_\_\_\_\_ video recorded (**I agree**)

*Initials*

\_\_\_\_\_ photographed (**I agree**)

*Initials*

**I do not agree**, on behalf of myself and my child, to be video recorded and photographed for the purpose of presentations and media publications of this research (please initial where applicable):

\_\_\_\_\_ video recorded (**I do not agree**)

*Initials*

\_\_\_\_\_ photographed (**I do not agree**)

*Initials*

### **Storage and Future use of data:**

Because it is not possible for us to know what studies may be a part of our future work, we ask that you give permission now for us to use your personal information without being contacted about each future study. Future use of your information will be limited to studies about children and their behaviors measured in this study (e.g., attachment to pets). If you agree now to future use of your personal information, but decide in the future that you would like to have your personal information removed from the research database, please contact Megan MacDonald at (541) 737-3273 or [megan.macdonald@oregonstate.edu](mailto:megan.macdonald@oregonstate.edu). Please initial where applicable:

**You MAY** store my information for use in future studies. \_\_\_\_\_

*Initials*

**You MAY NOT** store my information for use in future studies. \_\_\_\_\_

*Initials*

**Future contact:** We may contact you in the future for another similar study. You may ask us to stop contacting you at any time.

**Study Results:** Following the study activities, a summary of the study results will be shared with participants (via e-mail); these results will be for the entire study (not just your child's individual results).

## **5. WHAT ARE THE RISKS AND POSSIBLE DISCOMFORTS OF THIS STUDY?**

The possible risks and/or discomforts associated with the being in the study include no more risks than typical scratches or bruises that children may experience in traditional play. Most of the assessments in this study have been standardized and are commonly administered to children. It is possible that some of the questions indicated in the questionnaire(s) may make the participants uncomfortable or upset. Participants may disclose information that indicates they are experiencing anxiety, depression or are otherwise in distress.

The animal assisted physical activity facilitators have been trained and have extensive experience working with children with and without disabilities, and with animals. However, animals can sometime engage in unexpected behavior that could potentially lead to injury or distress. Cats will be screened for health and/or behavior problems prior to participation and are to be kept on leash in public areas at all times to minimize such risks, but unexpected risks associated with being near other cats or humans or participating in training are possible.

**Breach of Confidentiality:** There is a risk that we could accidentally disclose information that identifies you. There is a risk that other children/parents in the project may disclose information about your participation.

## **6. WHAT HAPPENS IF I AM INJURED?**

Oregon State University has no program to pay for research-related injuries. If you think that you have been injured as a result of being in this study, we would strongly encourage you to contact your physician.

## **7. WHAT ARE THE BENEFITS OF THIS STUDY?**

We do not know if you and your child will benefit from being in this study. However, your child may improve their social well-being and their relationship with their cat.

## **8. WILL I BE PAID FOR BEING IN THIS STUDY?**

You will be paid for being in this research study. You will receive a \$25 gift card during the assessments, which will occur three times (at the beginning of the study, about 6 weeks after the initial assessment and about 1 year after the initial assessment).

## **9. WHO IS PAYING FOR THIS STUDY?**

The National Institutes of Health (NIH) is paying for this research to be done.

## **10. WHO WILL SEE THE INFORMATION I GIVE?**

The information you provide during this research study will be kept confidential to the extent permitted by law. Most people outside of the study team will not see research information that includes your name or your child's name. This includes people who try to get your information using a court order. We could give out this information if you gave us permission. Research records will be stored securely and only researchers will have access to the records. If the results of this project are published, If the results of this project are published your identity will not be made public. For those participants who have opted to allow for the use of their images (video/photography) in presentations and media publications, identifiable information shared. As indicated in the optional video/photography section, it is possible that direct (e.g., child's name) or indirect (e.g., cat's name) identifiers might be shared through the video. Federal regulatory agencies and the Oregon State University Institutional Review Board (a committee that reviews and approves research studies) may

inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

Under Oregon law, researchers are required to report to the appropriate authorities any information concerning child abuse or neglect. The researchers may also report threats of harm to self or to others. In this instance, we will be required to share your and your child's information.

The sponsor of this project, the National Institutes of health, may see information from this study, but no identifiable information will be shared.

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.

**11. WHAT OTHER CHOICES DO I HAVE IF I DO NOT TAKE PART IN THIS STUDY?**

Participation in this study is voluntary. If you decide to participate, you are free to withdraw at any time without penalty. If you choose to withdraw from this study before it ends, the researchers may keep information already collected about you and this information may be included in study reports.

**12. WHO DO I CONTACT IF I HAVE QUESTIONS?**

If you have any questions about this research project, please contact: please contact: Megan MacDonald at (541) 737-3273 or [megan.macdonald@oregonstate.edu](mailto:megan.macdonald@oregonstate.edu)

If you have questions about your rights or welfare as a participant, please contact the Oregon State University Human Research Protection Program (HRPP) office, at (541) 737-8008 or by email at [IRB@oregonstate.edu](mailto:IRB@oregonstate.edu)

**13. ASSENT STATEMENT**

This research study has been explained to my child in my presence in language my child can understand. He/she has been encouraged to ask questions about the study now and at any time in the future.

**14. WHAT DOES MY SIGNATURE ON THIS CONSENT FORM MEAN?**

Your signature indicates that this study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

**Do not sign after the expiration date: March 13<sup>th</sup>, 2028**

Your Name (printed): \_\_\_\_\_

\_\_\_\_\_  
(Your Signature)

\_\_\_\_\_  
(Date)

\_\_\_\_\_  
(Signature of Person Obtaining Consent)

\_\_\_\_\_  
(Date)