

The UNIVERSITY OF CHICAGO
The Division of the Biological Sciences • The University of Chicago Medical Center

CONSENT/AUTHORIZATION FOR PARTICIPATION IN A RESEARCH PROTOCOL

Protocol Number: IRB22-1218

Name of Subject: _____
Medical History Number: _____

STUDY TITLE: Feasibility of a dog training therapy program in UC outpatient youth receiving psychiatric services

Doctors Directing Research: Dr. Kristen Jacobson and Dr. Karam Radwan

Address: 5841 S. Maryland, MC 3077, Chicago, IL 60637

Telephone Number: 773-834-0265

KEY INFORMATION

We are asking you to choose whether or not to volunteer your child for a research study about dog therapy programs for children. We will compare two types of dog therapy programs to see if they help children learn to control their behaviors and emotions.

The purpose of this section is to give you key information to help you decide whether to have your child participate. We have included detailed information after this section. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is above. In the below, 'you' may refer to you, or your child, as appropriate.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

By doing this study, we hope to learn how the dog therapy programs can affect participating children with emotional and behavioral problems. Specifically, we are interested in whether these programs impact children's ability to manage their emotions and behavior and how they feel about themselves. In this study, some children will be enrolled in a dog therapy program where they learn to train dogs and some children will be enrolled in a dog therapy program where they play with dogs. If you consent, your child will participate in this research study which will last about 6 weeks in the intervention, and up to 4 weeks before and after the intervention for data collection.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

Interacting with therapy dogs may help your child learn better control of their behaviors and emotions and may make your child feel better about themselves. Your child's participation will also help us better understand how interacting with therapy dogs can impact the behavior of children. For a complete description of benefits, refer to the Detailed Consent.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

You may choose not to provide consent for your child to participate in this study if you think your child would not like interacting with a therapy dog. For a complete description of risks, refer to the Detailed Consent.

DO YOU HAVE TO TAKE PART IN THE STUDY?

Taking part in this study is voluntary. If you decide to enroll your child in the study, it should be because you really want to volunteer. You or your child may choose not to participate at any time during the study. Your child will not lose any services, benefits or rights they would normally have if they choose to leave the study. The University of Chicago/University of Chicago Medical Center will not condition (withhold or refuse) treating your child on whether you sign this Authorization or revoke your authorization at a later time. If you or your child do not sign this form, your child will not receive the research-related intervention(s).

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Dr. Kristen Jacobson of the University of Chicago. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: 773-834-0265. You may also email her at kjacobs@bsd.uchicago.edu.

For questions about your rights as a research subject, please contact the University of Chicago BSD IRB at 773-702-6505.

OTHER KEY INFORMATION

Your child's physician will not be told whether or not your child is participating in this study. None of the research data will be entered into your child's medical record.

Your child's research results will not be shared with you, your child, or your child's physician.

In future, identifiers associated with your child's data could be removed from the data. The de-identified data could then be used for future research by our research team or other researchers without notifying you or asking your permission for this use.

DETAILED CONSENT

WHAT IS INVOLVED IN THE STUDY?

About 72 children aged 8-17, along with one of their parents/legal guardians, will take part in this study.

The study happens at the University of Chicago and at the Canine Therapy Corps dog training facility at 3918 W Fullerton Ave, Chicago, IL 60647.

If you decide to participate in this study, you and your child will each be asked to participate in an interview at the University of Chicago to obtain information on demographic characteristics, animal phobias and allergies, history of pet ownership and interactions with animals.

We will ask you to complete survey questionnaires on your attitudes towards pets, your parenting style, and your child's behavior problems. We may ask some of these questionnaires two times (once at the beginning of the study and once at the end of the study).

We will ask your child to:

1. Complete a short cognitive assessment at the beginning of the study to assess their ability to understand the study.
2. Wear a wristwatch for 15 minutes at the beginning of the study to measure your child's heart rate, blood pressure, and activity while resting.
2. Complete a questionnaire on their strengths and weaknesses in controlling their behavior, emotions, and problem solving two times (once at the beginning of the study and once at the end of the study).
3. Complete self-report survey on attitudes towards pets two times (once at the beginning of the study and once at the end of the study).
4. Complete self-report survey of self-esteem two times (once at the beginning of the study and once at the end of the study).
5. Complete two computer-assisted behavioral tasks assessing: 1) emotion regulation and 2) attention and impulsivity. Each task will be given two times (once at the beginning of the study and once at the end of the study).

We will review your child's medical records from the University of Chicago to make sure they are eligible for the study.

All children in the study will be participating in an 6-week dog therapy program that will be held at the Canine Therapy Corps dog training facility on evenings or weekends. Half of the kids will be in a dog training program, which meets weekly for 75 minutes. In this program children learn how to teach dogs obedience commands and participate in dog agility training. The other half of the kids will be in a dog education program, which meets weekly for 45 minutes. In this program, the children learn facts about dogs, watch therapy dogs do tricks, and play with the dogs for 15 minutes. A computer will randomly assign your child to the dog training or dog education program. This randomization program ensures that there is balance among gender and age in the two groups.

For children in both dog therapy programs, we will ask them to answer a short questionnaire about how they are feeling immediately before and immediately after each dog training session that they attend (up to 12 times).

The information provided by your child during the study will be confidential. Only designated project staff will have access to this information. All data collected directly from you and your child will be identified only by a study number. Any medical data will be entered directly into a secure, password-protected data entry system maintained by the University of Chicago.

In future, identifiers associated with your child's data could be removed from the data. The de-identified data could then be used for future research by our research team or other researchers without notifying you or asking your permission for this use.

The results from this study will not be shared with you.

Dr. Jacobson may decide to take your child off of the study without your consent if:

- Your child is unable to meet the requirements of the study;
- Your child's medical records indicate that they are not eligible for the study;
- Your child does not attend at least one of the dog therapy sessions;
- New information becomes available that indicates that participation in this study is not in your child's best interest; or
- If the study is stopped.

WHAT ARE THE RISKS OF THE STUDY?

There are risks of participating in this study. You or your child may find some of the interview or survey questions to be boring or embarrassing. You and your child can skip any questions that make you uncomfortable and can stop the study at any time.

Interacting with any animal carries some risk of physical injury. All therapy dogs have received special training to interact with people of all ages. There is always a canine behavior expert present during the dog therapy sessions to make sure sessions are conducted safely. If your child has a minor injury, like a scratch, there are medical supplies on-site at the Canine Therapy Corps facility that we can use to treat your child. We do not expect any serious physical injuries from participating in this study. Procedures to treat any serious injuries are described below.

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

Being in this study may help your child learn to control their emotions and behaviors and to feel better about themselves.

WHAT OTHER OPTIONS ARE THERE?

Instead of being in this study, you may choose to have your child not participate. The decision whether or not to have your child participate in this study will not impact any services or care that your child receives at the University of Chicago Medical Center.

WHAT ARE THE COSTS?

Clinical services provided during a clinical research study are either research-related or considered part of usual medical care for patients with your disease or condition. Tests, procedures, and activities that are ordered by your medical care team to monitor your disease or condition (whether you are participating in a clinical trial or not) are described as 'usual medical care'. 'Research-related' is the term used to describe any tests, procedures, or activities that you are being asked to undergo only because of your participation in this clinical research study.

You or your insurance will be financially responsible for the costs of your usual, ongoing medical care. This often includes regular visits with your doctor, lab tests, and other tests and procedures deemed medically necessary by your care team. Financial responsibilities for routine care may include deductibles and co-payments and this care will be subject to all the same requirements and restrictions of your insurance.

You will not be responsible for the costs of tests or services that are being performed solely for the purposes of this study and would not be performed if you were not participating in this clinical research study. This may include additional tests to answer a research question that are not required for your routine clinical care.

If you have questions about whether specific clinical services are research related or part of your usual medical care, please speak to your physician or research contact person.

WHAT HAPPENS IF I HAVE AN INJURY?

If your child suffers an unanticipated injury as a direct result of this research and requires emergency medical treatment, The University of Chicago Medical Center may provide treatment at the University of Chicago Medical Center at no cost to you or your child. Costs of related non-emergency care for an unanticipated research injury will be covered if that care is provided at the University of Chicago Medical Center. You must notify Dr. Jacobson as promptly as possible after injury in order to receive this care. An injury is “unanticipated” if it is not one of the known effects of a study drug, medical device or procedure. If you think that your child has suffered a research related injury, you must let Dr. Jacobson know right away.

In the event of an emergency, you should take your child to the nearest emergency room or call 911.

WILL I BE PAID FOR MY PARTICIPATION?

You and your child will be paid for participating in this study. Payments will be made in cash for in-person visits and with gift-cards if evaluation activities are completed online.

- You and your child will each receive \$20 for participating in the baseline assessment at the beginning of the study (\$40 total).
- You and your child will each receive \$25 for participating in the follow-up assessment at the end of the study (\$50 total).
- Your child will receive \$30 for each of the 6 dog therapy sessions that they attend (\$180 total).

The maximum total amount of payment that your family will receive for participating in this study is \$270.

We will also give you a parking voucher for each visit to the University of Chicago.

We will give you \$20 for transportation to each dog training session (maximum of \$120 for transportation).

WHAT ABOUT CONFIDENTIALITY?

There is a risk of potential loss of confidentiality. To minimize this risk, study records that identify your child will be kept confidential. We will use a study number to identify your child.

All interview and self-report survey data collected from your child for this study will be entered directly

into a University of Chicago database using secure, password-protected project tablets. Data are entered via secure online links that are only accessible to the study Investigators and research project staff. All data collected directly from your child will be identified only by their study number.

Data collected during the neuropsychological tasks are either stored directly on a secure, centralized data storage cloud or will be entered directly into a secure, password-protected data entry system maintained by the University of Chicago. Neuropsychological data will be linked to the youth participant using the study ID.

Any medical data about your child obtained for this study will be entered directly into a secure, password-protected data entry system maintained by the University of Chicago. No names or identifying information will be recorded. Any copies of the medical records will be destroyed after data entry.

Your child's physician will not be told whether or not your child is participating in this study. None of the research data will be entered into your child's medical record.

During this study, Dr. Jacobson and her research team will collect protected health information (PHI) about your child for the purposes of this research. The research team includes the individuals listed on this consent form and other personnel involved in this study at the University of Chicago. Protected Health Information (PHI) consists of any health information that is collected about your child, which could include your child's medical history and new information collected as a result of this study. Some of this information may come from your child's medical record. The information to be used on this study includes your child's name, birthdate, and medical record number. We will use these identifiers to be certain that your child is eligible to participate in the study, to check on your child's health status, and for long term follow-up.

Your child's records may be reviewed by federal agencies whose responsibility is to protect human subjects in research and Office of Human Research Protections (OHRP). Representatives of the University of Chicago, including the Institutional Review Board (a committee that oversees the research) and the Office of Clinical Research may also view the records of the research.

Once information is shared outside the University of Chicago, please note that your child's identifiable health information may be shared with someone else. The same laws that the University of Chicago must obey may not protect your child's health information.

This consent form will be kept by the research team for at least five years. The study results will be kept in your child's research record and be used by the research team until completion of this study. At the time of study completion, the information identifying you and your child will be removed from study results.

Data from this study may be used in medical publications or presentations. Your child's name and any other identifying information will be removed before this data is used. If we wish to use identifying information in publications, we will ask for your approval at that time. We may also share de-identified data with collaborators or others for research purposes.

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.

To help us protect your child's privacy, the National Institutes of Health (NIH) has issued a Certificate of Confidentiality for this research. With this Certificate, the researchers cannot be forced to disclose information that may identify you or your child, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you or your child, except as explained below. The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself, your child, or your child's involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

There are specific circumstances when the Certificate of Confidentiality does not prevent researchers from disclosing voluntarily, without your consent, information that would identify your child as a participant in the research. This exception includes your child's disclosure of information that she/he is currently being abused or neglected, is currently being put at serious risk of abuse/neglect, or is at risk of harm to him/her self. Such information will be reported to the Department of Children and Family Services as required by law. Your child will be advised of this requirement prior to being asked to give assent to be interviewed.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

If you choose to no longer have your child be in the study you must inform Dr. Jacobson in writing at the address on the first page. Dr. Jacobson may still use information that was collected from your child prior to your written notice.

You will be given a signed copy of this document. Your authorization to use and disclose your child's health information does not have an expiration date.

ASSENT (AGE 12-17)

CHILD SUBJECT

The research project and the procedures associated with it have been explained to me. The experimental procedures have been identified and no guarantee has been given about the possible results. I will receive a signed copy of this consent form for my records.

I agree to participate in this study. My participation is voluntary and I do not have to sign this form if I do not want to be part of this research study.

Signature of Subject: _____

Date: _____ Time: _____ AM/PM (Circle)

CONSENT

PERSON OBTAINING CONSENT

I have explained to _____ the nature and purpose of the study and the risks involved. I have answered and will answer all questions to the best of my ability. I will give a signed copy of the consent form to child's parent/guardian.

Signature of Person Obtaining Consent: _____

Date: _____ Time: _____ AM/PM (Circle)

INVESTIGATOR/PHYSICIAN:

Signature of Investigator/Physician: _____

Date: _____ Time: _____ AM/PM (Circle)

PARENT/GUARDIAN/ OR LEGALLY AUTHORIZED REPRESENTATIVE:

I give my permission for my child/relative/the person I represent to participate in the above described research project.

Signature of Parent/Guardian/ or Legally Authorized Representative: _____

Date: _____ Time: _____ AM/PM (Circle)