

TITLE: Assent to Participate in a Research Study Adolescent Participants age 15-17

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**University of North Carolina at Chapel Hill
Assent to Participate in a Research Study
Adolescent Participants age 15-17**

Consent Form Version Date: August 12, 2022

IRB Study # 19-1911

Title of Study: Animal Assisted Therapy's Effects on Dental Patients

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Principal Investigator Department: Orthodontics

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CONCISE SUMMARY

This is a research study to explore ways of reducing fear and discomfort when children see the dentist. If enrolled, you will be asked to do a calming activity before your dental visit which could be coloring a picture or being introduced to a therapy animal in the Graduate Orthodontic or Pediatric Clinic waiting room prior to your dental appointment or in the dental clinical lab located at UNC Adams School of Dentistry. You will be asked to fill out two surveys, consisting of approximately 10-15 questions, that will require approximately 5-10 minutes of your time before and after the appointment. All participants will be outfitted with a small wristband device (a Shimmer device) that silently tracks their heartrate, breathing rate, sweating and skin temperature. We will also collect a video of your child during the dental visit. All results are wirelessly collected and stored on a secure server throughout the visit. Salivary (spit) samples will be collected during the visit to measure stress hormones. Your child will also be asked to answer some questions about their experience at the dentist. There is not an additional follow up regarding the study, and you are only eligible to participate once.

There are minimal risks to participating in the study. There is a potential risk regarding breach of confidentiality of your child's personal health information. At UNC, we operate on a secure network to ensure that your data is protected.

A benefit of participating is a \$30 gift card that we are using to incentivize patients and parents to participate; or if eligible, your child will receive a free oral exam, an oral exam report, referral to a pediatric dental provider if needed, and a dental cleaning for your participation in the study in addition to the \$30 gift card.

There is no additional follow up regarding the study, and your child is only eligible to take the surveys once. If you are interested in learning more about this study, please continue reading below.

What are some general things you should know about research studies?

You are being asked to take part in a research study. Your parent or guardian, needs to give permission for you to be in this study. You do not have to be in this study if you don't want to, even if your parent has already given permission. To join the study is voluntary. You may choose

not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. If you decide to participate you will receive a \$30 gift card for participating.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study. You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?

The purpose of this research study is to determine the effect of Animal Assisted Therapy on patient physiologic biometrics, and perceptions of anxiety, satisfaction, and future expectations in an orthodontic clinic.

You are being asked to be in the study because you are currently seeking to receive treatment at the University of North Carolina Graduate Orthodontics or Pediatrics Dental Clinic, or because you or your parent showed interest in participating in this study.

Are there any reasons you should not be in this study?

You should not be in this study if you are outside the age range of 4-17 years old, if you has an allergy to dogs or toothpastes, have had a previous traumatic experience with a dog, receiving limited, phase I, or clear aligner treatment, or have a Frankl score outside the range of 2-4.

How many people will take part in this study?

There will be approximately 180 people in this research study.

How long will your part in this study last?

The only additional time commitment we need from you is the time to fill out a short 10-15 question survey before and after their already scheduled dental appointment.

What will happen if you take part in the study?

When you enter the waiting room on the day of your dental appointment, you will be given a Shimmer device that is fitted to your wrist. Then you will be asked to do a calming activity before your dental visit which could be coloring a picture or being introduced to a therapy animal. You will be brought back to the clinic setting, dental treatment/exam will occur and then you will fill out a short survey after the treatment/exam has been completed. We will also collect a video of your during the dental visit. All results are wirelessly collected and stored on a secure server throughout the visit. Salivary (spit) samples will be collected during the visit to measure stress hormones.

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. If willing to participate, you will receive a \$30 gift card for being in this research study. If eligible, you might receive a free oral exam, a free oral exam report (summarizing dental findings), a referral to a pediatric dental

provider if needed, and a tooth cleaning in addition to the \$30 gift card for your participation in the study.

What are the possible risks or discomforts involved from being in this study?

There may be uncommon or previously unknown risks. A possible risk that you should be aware of is a possible breach of confidentiality, meaning that someone could access your personal information. This risk is minimal as we have systems in place for your safety and to protect you and your information. You should report any problems to the researcher.

What if we learn about new findings or information during the study?

You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

How will information about you be protected?

Participants will not be identified in any report or publication about this study. We may use de-identified data and/or specimens from this study in future research without additional consent.

Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

What if you want to stop before your part in the study is complete?

You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

Will you receive anything for being in this study?

Each participant that is willing to participate will be given a \$30 gift card. If eligible, you might be given a free oral exam report (summarizing findings), a referral to a pediatric dental provider if needed, and a dental cleaning in addition to the \$30 gift card for your participation in the study.

Will it cost you anything to be in this study?

It will not cost you anything to be in this study.

What if you have questions about this study?

You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research participant?

All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you

would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

Your signature if you agree to be in the study

Date

Printed name if you agree to be in the stud

Signature of Research Team Member Obtaining Assent

Date

Printed Name of Research Team Member Obtaining Assent