

Children's Hospital Los Angeles
PERMISSION FOR CHILD TO PARTICIPATE IN A RESEARCH STUDY

Sensory Adapted Dental Environments to Enhance Oral Health in Children with Autism Spectrum
 Disorder (the SADE-2 study)

Research On How Children Feel When They Get Their Teeth Cleaned

Subject's Name:	
CHLA #:	
Birth Date:	

• **INTRODUCTION**

Your child is invited to participate in a research study conducted by Dr. Sharon Cermak, Ed.D., OTR, FAOTA from the Mrs. T.H. Chan Division of Occupational Science and Occupational Therapy at the University of Southern California, and Dr. Jose Polido, DDS, MS, from the Division of Dentistry at Children's Hospital Los Angeles (CHLA). This research is sponsored by the National Institute of Dental and Craniofacial Research. Your child is invited to participate in this study because your child is undergoing a routine dental cleaning and is diagnosed with an autism spectrum disorder (ASD). About 184 children will take part in the study. Participation in this study is completely voluntary. Please read the information below, and ask questions about anything you do not understand, before deciding whether or not to allow your child to participate.

• **PURPOSE OF THE STUDY**

This study is about the possible influence the dental environment may have on a child's teeth cleaning experience. From observing and recording your child's responses during a regular dental cleaning and a dental cleaning in which the sensory features of the dental environment are changed (i.e. your child will hear music, lighting will be dimmed, and your child will wear a special vest that is calming), we hope to gain knowledge to create a safer and less anxiety-producing treatment.

• **PROCEDURES**

Participation in this research will last between 4-9 months.

If you and your child volunteer to participate in this study, the following will occur:

1. If your child is already seen at Children's Hospital Los Angeles (CHLA), we will review and collect information about your child's dental history and medical history. We will see if your child has an autism spectrum disorder (ASD) diagnosis in his file and if your child has diagnoses that might make this study inappropriate for your child. If your child is not a CHLA client, we will do this on the phone with you.
2. If your child is eligible to participate, we will schedule a 1 ½ hour home visit with you (if you prefer, this can be scheduled at CHLA or your local library). During this visit, we will review the research protocol with you, answer any questions you may have, and if you are interested in participating, you will sign a Consent form. The following will also occur:

- a. You will complete a set of questionnaires about your child, including about his/her responses to going to the dentist. This will take approximately 30-60 minutes to complete.
 - b. Your child will be asked to answer some questions about how relaxed or anxious they are at the dentist. This should take 5-10 minutes.
 - c. You will complete a “contact information” form so we can contact you to schedule and remind you of appointments. This form will have your contact information (name, address, phone number and email address) as well as the contact information of two family members or close friends in the case we cannot contact you.
3. We will schedule a 1 hour visit for you at CHLA to confirm your child’s ASD diagnosis and to assess your child’s cognitive ability. During this visit, the following will occur:
- a. The psychologist on our team will perform a test known as the Autism Diagnostic Observation Schedule (ADOS) at no cost to you. This is done for research purposes only and does not affect the services your child receives. The test will take approximately 45 minutes to complete and will be video-recorded. If your child has previously had the ADOS administered at the CHLA USC Center for Excellence in Developmental Disabilities, we will accept the ASD confirmation and the study results from that previous assessment. The recordings will be destroyed within one year following completion of the study.
 - b. Your child will be given a short cognitive screening test known as the Wechsler Abbreviated Scale of Intelligence-2. This takes about 20 minutes.
 - c. If your child meets the ASD criteria for the study, he or she will continue to the dental visits part of the study. If your child does not meet these criteria and is a CHLA dental client, your previously scheduled dental cleaning will continue as usual but your child will not continue as a research participant and will not participate in the study’s visits. If your child does not meet the ASD criteria for the study and is not a CHLA dental patient, he or she will not participate in the study and will not have dental visits scheduled.
 - d. We will send you the results of these two tests in the mail following their completion. This information is confidential and will be shared only with you.
4. All children in the research study will participate in two separate dental cleanings at CHLA, approximately 4-6 months apart. Each of these cleanings will take approximately 15-40 minutes to complete. One cleaning will be in the regular dental environment, one will be in the sensory-adapted dental environment. We will use a computer to decide at random which one is first. Your child will have an equal chance (like the flip of a coin) of starting with either type of dental environment.
- a. Both of your child’s dental cleanings will be video-recorded. We are not able to cover or hide your child’s face on the video because of the type of analysis we will be conducting on these images.
 - b. During both dental cleanings, your child will have two electrodes attached to the palm of his or her hand. The electrodes are like band-aids and do not hurt to wear. They will record electrical changes in the skin.
 - c. We will measure the amount of plaque (bacteria) on your child’s teeth with a camera inside the mouth before and after each dental cleaning.

- d. In the regular dental environment, your child's dental cleaning will be the same as a routine cleaning; except your child will be wearing electrodes, we will take photographs inside your child's mouth, and the procedure will be video-recorded. In the sensory-adapted dental environment, the lights in the office will be dimmed, calming music will be played, and a special vest will be wrapped around your child to help calm him/her. Your child will also be wearing electrodes, will have photographs taken inside his/her mouth, and the procedure will be video-recorded.
 - e. If your child agrees to participate, your child (if able) will complete a short survey before his/her dental cleaning and a short survey following dental treatment. This will take about 5-20 minutes before the dental cleaning and about 2-5 minutes after the dental cleaning. Your child will answer questions about their fear, pain, and anxiety when they visit the dentist.
 - f. The dentist performing your child's dental cleaning will complete a short questionnaire about your child's treatment that day.
5. If, during the study, your child needs any dental treatment that involves giving them medicine, we will also collect the billing data from your child's records for research and analysis. We will not be collecting credit card information.

Repository

Information (including videos) collected as part of this research will be used to create a repository. Other researchers may access this data in the future to answer additional research questions about children with autism.

• **POTENTIAL RISKS AND DISCOMFORTS**

Your child may be self-conscious about being videotaped or answering questions or feel uncomfortable with electrodes attached to his/her hand.

There is the potential of unintentional disclosure of confidential information, although we take every precaution to protect your privacy.

There is a possibility you may feel uncomfortable answering some of the questions; if you are uncomfortable you may choose to not answer that question.

The sensory adapted dental environment, although calming for most children, may make some children feel uncomfortable. For example, the lights are dimmed so children who are afraid of the dark may initially experience some concern. Deep pressure, such as that provided by the butterfly wrap, has been used by occupational therapists for many years, and the butterfly has been used with more than 70 children with no negative effects. However, the butterfly does restrain your child such that it reduces his or her ability to move his/her arms, legs and body freely. As such, it may cause some children some anxiety. Your child will receive a social story ahead of time describing the different parts of the intervention and showing the butterfly and explaining its use. However, if you or your child is uncomfortable with any part of the procedure, you may ask to have it discontinued and we will immediately do so.

There may be additional risks to participation in this study that we do not know about and therefore cannot describe.

- **ANTICIPATED BENEFITS TO SUBJECTS**

Your child may find the dental cleaning with low lights, music, and a hugging vest to be calming and reduce his or her anxiety.

Your child will have two dental cleanings, during the study period.

- **ANTICIPATED BENEFITS TO SOCIETY**

The results of this study may contribute to our knowledge of how children experience routine dental cleanings and whether we can reduce children's fear and anxiety by modifying the dental environment. Learning more about children's responses to dental cleanings will make it easier for children to get their teeth cleaned at the dentist and improve their health.

- **ALTERNATIVES TO PARTICIPATION**

The alternative to participating in this research study is for your child to receive preventive dental care in a standard dental environment at his or her regular dental clinic.

- **PAYMENT FOR PARTICIPATION**

You and your child will receive compensation following participation in this study.

Compensation will be as follows:

Questionnaires and Autism Assessment

- You will receive \$40 cash at the home visit for answering the study questions.
- You will receive \$50.00 cash (\$40 plus \$10 parking or transportation) following administration of the Autism Diagnostic Observation Schedule (ADOS) and cognitive testing at CHLA.

Dental Cleanings:

- You will receive \$50.00 cash (\$40 plus \$10 parking or transportation) for successful completion of *each* of the first and second dental cleanings. In addition, your child will be able to choose a small gift from our Treasure Chest at the end of each visit.

- **FINANCIAL OBLIGATION**

This research study is funded by the National Institute of Dental and Craniofacial Research. Participants and their families are not responsible for the oral care costs completed for research purposes (child's second oral exam, cleaning, and fluoride application).

If you have insurance, you may be billed for the first cleaning, but the second will occur at no cost to you. If you do not have insurance and meet eligibility criteria, the cost for both dental cleanings will be covered by the study. This research study does not include other services that your child may need.

The Autism Diagnostic Observation Schedule and short cognitive screener will be completed by a CHLA psychologist at no cost to you or your insurance.

Date: 02/13/17

IRB#: CHLA-15-00047

• EMERGENCY CARE AND COMPENSATION FOR INJURY

It is important that you promptly tell the study doctor if you feel that your child has been injured because of taking part in this study. You can tell the study doctor in person, or call him/her at (323) 442-2879 or 310-433-4131 (Mobile). If your child is injured or becomes ill as a direct result of participating in this study, CHLA will provide necessary medical treatment. The costs of treatment will be billed to you or your child's insurer like other medical costs. Neither CHLA nor USC have programs to provide you with any additional compensation as a result of any injuries. You do not waive any liability rights for personal injury by signing this form.

• PRIVACY AND CONFIDENTIALITY

Members of the research team and your dentist will know that your child is a research subject. All results will be kept confidential, but may be made available to you, and/or your child's physician or dentist if you wish. Authorized representatives of the National Institute of Dental and Craniofacial Research, the Department of Health and Human Services, and the CHLA Institutional Review Board may need to review records of individual subjects. As a result, they may see your child's name; but they are bound by rules of confidentiality not to reveal your child's identity to others. No information about your child or provided by you about your child during the research will be disclosed to others without your written permission, except:

- if necessary to protect your rights or welfare (for example, if you are injured and need emergency care); or
- if required by law (i.e., child or elder abuse, harm to self or others, reports of certain infectious diseases).

When the results of the research are published or discussed in conferences, no information will be included that would reveal your child's identity unless you agree to let us use the video recordings of your child during the dental cleaning for educational purposes. We will ask you for your permission for this at the end of this form.

All questionnaires, physiological data, intraoral photographs, and video recordings will be labeled with an identification number. We keep a record that matches the identification number with your child's name. This information and all the questionnaires, physiological data, intraoral photographs, and video recordings will be stored in a locked filing cabinet to prevent access by unauthorized personnel. Parents have the right to view video recordings for as long as they are in the researcher's possession (a maximum of six years).

• PARTICIPATION AND WITHDRAWAL

Your child's participation in this research is VOLUNTARY. Your choice about whether or not to permit your child to participate will have no effect on your child's care, services or benefits at Children's Hospital Los Angeles. If you agree to have your child participate, but later decide to withdraw him/her from this study, you may do so without affecting you or your rights to health care, services or other benefits at Children's Hospital Los Angeles. Please contact the Principal Investigator if you wish to withdraw your child from the study.

- **WITHDRAWAL OF PARTICIPATION BY THE INVESTIGATOR**

The investigator may withdraw your child from participating in this research if necessary to protect you or your child's health or if other situations arise that make it necessary to do so. The investigators, Dr. Sharon Cermak or Dr. Jose Polido, will make the decision and let you know if it is not possible for you to continue. The decision may be made either to protect your health and safety, or because it is part of the research plan that people who develop certain conditions may not continue to participate.

- **NEW INFORMATION**

If there is significant new information found during the course of the study or the study plan is changed in ways that might affect your decision to allow your child to participate in the study, you will be informed, and your permission to continue your child's participation in the study may be obtained again.

- **HOW TO OBTAIN INFORMATION**

Daytime, Monday through Friday, 8:00 A.M. through 4:30 P.M. you may call Dr. Sharon Cermak at (323) 442-2879 or 310-433-4131 (Mobile).

Evenings, nights, weekends or holidays you may call the hospital number, (323) 660-2450 and ask for the Division of Dentistry Service doctor on-call.

- **FINANCIAL INTEREST OF THE INVESTIGATOR**

Funding for this research study is provided by the National Institute of Dental and Craniofacial Research. The funding is used to support the activities of the Division of Dentistry at CHLA, the Mrs. T.H. Chan Division of Occupational Science and Occupational Therapy at the University of Southern California, and provide stipends to families. Compensation to CHLA is not based upon the number of research subjects enrolled. If your dentist is an investigator for this study s/he is interested in both your healthcare and the conduct of this research. You are not under any obligation to participate in a research study conducted by your dentist.

- **RIGHTS OF RESEARCH SUBJECTS**

You may withdraw your permission for your child's participation from this study at any time and discontinue participation without penalty. You are not waiving any legal claims, rights or remedies because of your child's participation in this research study. If you have questions regarding the rights of research subjects or if you have complaints or concerns about the research and cannot reach the Principal Investigator; or just want to talk to someone other than the Investigator, you may call Children's Hospital Los Angeles, Human Subjects Protection Program office at (323) 361-2265.

SIGNATURE OF PARENT(S)/LEGAL GUARDIAN(S)

Your signature(s) below indicates

- You have read this document and understand its meaning;
- You have had a chance to ask questions and have had these questions answered to your satisfaction;
- You agree to your child's participation in this research study;
- You agree to your own participation in this research study; and
- You will be given a signed copy of this form.

○ **Please initial next to ONE choice**

_____ I AGREE to allow my child's full-face video-recording of the dental visits or autism assessment to be used in academic presentations, publications, or training.

_____ I DO NOT AGREE to allow my child's full-face video-recording of the dental visits or autism assessment to be used in academic presentations, publications, or training.

- If you would be willing to be contacted by phone or by e-mail to be invited to participate in a future research project **please initial here** _____.

Print Name(s) of Parent(s)/Legal Guardian(s)

Signature of Parent/Legal Guardian

Date

Signature of Parent/Legal Guardian

Date

SIGNATURE OF INDIVIDUAL OBTAINING CONSENT
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I have explained the research to the subject and/or the subject's parent(s)/legal guardian(s) and have answered all of their questions. I believe that they understand all of the information described in this document and freely give assent/consent/permission to participate.

Print Name of Individual obtaining consent

Signature of Individual obtaining consent

Date

SIGNATURE OF WITNESS (if applicable)

My signature as witness indicates that the parent(s)/legal guardian voluntarily signed this permission form in my presence.

Print Name of Witness

Signature of Witness

Date

SIGNATURE OF INTERPRETER (if applicable)

Print Name of Interpreter

Signature of Interpreter

Date

Study Team Instructions: Only complete the section below if assent is required, and either only verbal assent was obtained from the subject or assent was not obtained from the subject.

Please check appropriate box and sign below.

☐ The undersigned, _____, hereby certifies that verbal assent was obtained from the subject.

☐ Assent was not obtained from the subject. (Please state the reason. Examples include: subject is an infant; subject is comatose; subject lacks cognitive abilities to understand the information; etc.)

Date:

Time:

Signature

Routing of signed copies of the form:

- 1) Give to the parent(s)/legal guardian(s) (copy)
- 2) Place in the CHLA Medical Record, if applicable (copy)
- 3) Place in the Principal Investigator's research file (original)