

**UNIVERSITY OF CALIFORNIA, IRVINE
CONSENT TO ACT AS A HUMAN RESEARCH SUBJECT**

Improving Dental Care and Oral Health in Children with ASD

You and your child are being asked to participate in a research study. Participation is completely voluntary. Your participation will not affect any clinical care you receive. You may decide to stop participation at any time. Please read the information below and ask questions about anything that you do not understand. A researcher listed below will be available to answer your questions.

In the instance of parental permission, “You” refers to “Your child.”

Lead Researcher

Rachel Fenning, PhD
Assistant Clinical Professor
Center for Autism and Neurodevelopmental Disorders (CAND)
Department of Pediatrics, UCI School of Medicine
949-267-0417 / rfenning@uci.edu

Faculty Sponsor

Robin Steinberg-Epstein, MD
Clinical Professor
Center for Autism and Neurodevelopmental Disorders (CAND)
Department of Pediatrics, UCI School of Medicine
949-267-0427 / rsteinbe@uci.edu

24-Hour Telephone Number/Pager: 562-533-4147

Other Researchers

Kelly McKinnon, MA, BCBA

Jacquelyn Moffitt, BA
Meghan Orr, BM
Research Personnel, UCI CAND

Richard Spaulding, MS, DDS
Richard Udin, DDS
John Guijon, DDS
Healthy Smiles for Kids of Orange County

STUDY LOCATIONS:

University of California-Irvine, Healthy Smiles for Kids of Orange County, California State University, Fullerton

STUDY SPONSOR:

Autism Intervention Research Network on Physical Health

WHY IS THIS RESEARCH STUDY BEING DONE?

This is a study to compare the efficacy of an established dental toolkit and a combined program involving the dental toolkit and parent-mediated behavioral intervention on improving home dental hygiene and oral health for children with autism spectrum disorder.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 85 families will consent to take part in the research at UCI. A total of approximately 118 families will be asked to participate across all study sites.

AM I ELIGIBLE TO PARTICIPATE IN THIS STUDY?

Please note this may not be a complete list of eligibility criteria. We have included a few examples of study criteria to help you better understand how your eligibility in the study will be determined; your study team will go through the study eligibility criteria with you to verify if you qualify for participation in this study.

Inclusion Requirements

You can participate in this study if your child:

1. Is between age 3 years and 13 years, eleven months at study entry
2. Has a current diagnosis of ASD
3. Has not received dental screening or dental exams within the previous 6 months
4. Is not currently participating in or planning to participate in non-study adaptive behavior intervention or therapies focused on dental care
5. Has underserved status (Medicaid insurance). If you have Medicaid eligibility and private dental insurance for your child, you may still be able to participate in this study if our partner dental site, Healthy Smiles for Kids of Orange County, is able to bill your private dental insurance

Exclusion Requirements

You cannot participate in this study if:

1. Your child has an acute dental condition requiring emergency treatment
2. Your child is experiencing significant oral health complications as a side effect of certain medications that may affect oral and gingival health such as medications used to treat seizure disorders, long-term use of steroid medications, and certain medications used to suppress the immune system or treat high blood pressure.
3. There is anything that, in the opinion of the Site Investigators, would place you or your child at unwarranted risk or materially reduce your contribution to the study aims due to inability or refusal to adhere to study procedures and follow-up

HOW LONG WILL THE STUDY GO ON?

For all families, study participation includes 4 visits (1 clinic visit at The Center for Autism and Neurodevelopmental Disorders and 3 dental office visits at Healthy Smiles for Kids) over a period of 6 months. Families selected to receive the intervention will also participate in a 10-week program that includes treatment sessions at the Center for Autism and Neurodevelopmental Disorders, coaching sessions at home and at Healthy Smiles for Kids, as well as follow-up phone sessions.

WHAT PROCEDURES ARE INVOLVED WITH THIS STUDY?

Before you can participate in the main part of the study...

You will need to have “screening” exams, tests or procedures. The screening process helps the researchers decide if you meet the study requirements listed below. Procedures will include:

- **Verification of study eligibility**
- **Answering questions about your child’s experience with dental care**
- **Direct testing of your child to confirm ASD diagnosis**

Verifying study eligibility will occur through an initial screening and through participation in two baseline visits, one at the Health Smiles dental clinic and one at the UCI Center for Autism and Neurodevelopmental Disorders. These visits include the following:

1. Baseline Dental Exam

- *Your child will have a dental visit to assess oral health and to rule out the need for emergency dental treatment. The visit will use visual inspection and standard dental procedures.*
- *Behavioral procedures and medical supports are routinely used during pediatric dental exams for children with ASD. The use of any behavioral procedure or medical support will be clinically determined at the discretion of the treating dentist, and will not be dictated or influenced by this research study. Some procedures may require a separate clinical consent. You may decide not to consent to these procedures. This will not affect your participation in this study.*
- *The dental visit will be videotaped to allow researchers to observe your child's behavior.*
- *You will complete a brief questionnaire about your experiences and your child's behaviors related to the dental office visit.*

2. Baseline Clinic Visit

- *Your child will receive direct testing to confirm ASD diagnosis and assess intellectual functioning.*
- *The clinic visit will be videotaped to allow researchers to observe your child's behavior.*
- *You will also be asked to complete an interview to help researchers better understand your child's everyday experiences and needs.*
- *You will also complete questionnaires related to: demographic information, your child's past dental history, your child's experiences with dental care at home and at the dental office, as well as your child's current behaviors. We will also ask you to complete questionnaires so that we can better understand your experience as a parent.*

During the main part of the study...

If the screening exams, tests and/or procedures show that you can continue to be in the study, and you choose to take part, then you will have the opportunity to take part in the main study, which includes...

3. The Autism Speaks Dental Toolkit

- *All participants in the study will receive the Autism Speaks Dental Toolkit. The Dental Toolkit is a written guidebook designed to help families support tooth brushing and oral health for children with ASD. The Dental Toolkit provides ideas about how to get started with dental care at home, tips for brushing and flossing children's teeth, and strategies for preparing for dental office visits, including a picture schedule of the dental visit.*

4. Intervention

- *About half of the families participating in the main study will also receive an additional intervention at the UCI Center for Autism. Families will be selected at random (like the flip of a coin) for participation in the intervention after the screening and baseline visits are completed.*
- *If your family is selected to receive the additional intervention, you will also participate in:*

- *5 treatment sessions at the UCI Center for Autism. These treatment sessions will focus on helping your child with tooth brushing and flossing at home and on preparing for dental office visits. Your family will meet individually with a study therapist during these sessions, which will last approximately 75 to 90 minutes.*
- *1 approximately 60-minute treatment session at your home, with your study therapist. This home coaching session will focus on helping your child with tooth brushing.*
- *1 approximately 60-minute treatment session at the Healthy Smiles dental clinic with your study therapist. This session will focus on helping your child prepare for visiting the dentist.*
- *4 follow-up booster sessions by telephone (1 optional treatment session at home). The phone booster sessions will provide an extra opportunity to talk with your study therapist about home tooth brushing and flossing, and plans for your child's dental office visits.*

5. Three and Six Month Follow-up Sessions

- *All participating children will receive dental visits to assess oral health. The visits will use visual inspection and standard dental procedures.*
- *Behavioral procedures and medical supports are routinely used during pediatric dental visits for children with ASD. The use of any behavioral procedure or medical support will be clinically determined at the discretion of the treating dentist, and will not be dictated or influenced by this research study. Some procedures may require a separate clinical consent. You may decide not to consent to these procedures. This will not affect your participation in this study.*
- *The dental visit will be videotaped to allow researchers to observe your child's behavior.*
- *You will complete a brief questionnaire about your experiences and your child's behaviors related to the dental office visit.*
- *We will also ask you to complete questionnaires related to your child's home dental behavior, your child's general behaviors, as well as questionnaires that will help us to better understand your experience as a parent.*
- *At your six-month visit, you will be asked to complete a follow-up interview to help researchers better understand your child's everyday experiences and needs.*

You will be asked not to participate in any non-study dental exams or screenings for the duration of the study except as needed in the case of an emergency.

WHAT ARE THE POSSIBLE SIDE EFFECTS OR RISKS RELATED TO THE STUDY?

This study involves minimal risk. There is a risk of loss of privacy. During data collection, identifying information (name, contact information) is obtained. This creates a risk of breach of confidentiality if this information inadvertently became public.

You will be assigned to a study group by chance (like a coin flip) rather than by a medical decision made by the researchers. The treatment you receive may prove to be less effective or to have more side effects than the other study group, or than standard treatments available for your condition.

Participants in the combined intervention may experience some frustration or negative emotion related to the training sessions and practice activities that are part of the intervention. The intervention is designed to adequately identify and address these emotions.

You may become upset or uncomfortable when answering questions about your child's behaviors. You do not have to answer any questions that make you uncomfortable and you are invited to discuss any concerns with the research team using a 24-hour phone line that will be provided.

You may experience frustration when trying to get your child to engage in at-home dental behaviors. You may also experience negative emotion when observing your child's dental visit. Your child may experience anxiety or behavioral challenges as part of the dental visit. You may decide to terminate the dental visit at any time.

You should talk to the research team about any concerns you have while taking part in the study.

ARE THERE BENEFITS TO PARTICIPATING IN THIS STUDY?

Participant Benefits

All families will receive the Autism Speaks Dental Toolkit. Approximately half of the families participating in this study will also receive an intervention directly focused on supporting the participating child's tooth brushing and flossing at home, and on preparing the child for dental office visits.

Benefits to Others and Society

This study will help researchers learn more about the effect of the Autism Speaks Dental Toolkit and a parent-mediated behavioral intervention on home dental care and oral health outcomes for children with autism spectrum disorder. It is hoped that this information will help in the treatment of future children with autism spectrum disorder who experience difficulty with home dental hygiene and visits to the dentist.

WHAT OTHER CHOICES DO I HAVE IF I DON'T WANT TO PARTICIPATE?

If you decide not to participate, or if you withdraw from this study before it is completed, your other choices may include:

- Getting no treatment
- Getting standard treatment for your condition without being in a study.
- Getting a different experimental treatment/taking part in another study.

WILL I BE PAID FOR TAKING PART IN THIS STUDY?

Compensation

All participants who meet inclusion criteria for study enrollment will receive an electric toothbrush and a 6-month supply of toothbrush heads, fluoridated toothpaste, and flossers. We will also provide materials to assist with oral desensitization to dental office equipment (i.e., plastic mirror). Upon request, families will receive a brief written summary of results from child testing completed at baseline. In addition, participants will receive compensation in the form of gift cards for completion of the study protocol as outlined below.

Families selected to participate in the intervention (plus follow-up phone sessions) will receive up to \$500.00 in compensation over 6 months of study participation. Families will be compensated \$25 for each baseline visit (\$50 total) and \$30 for each of the remaining 9 in-person visits: the 7 in-person treatment sessions and the follow-up dental visits at 3 months and 6 months. An additional \$20 for each of the 9 completed in-person visits will be reserved for families and paid out at the completion of the final 6-month follow-up dental visit (an additional \$180). We will also provide childcare for families participating in the parent-training intervention.

Families selected to receive only the Autism Speaks Dental Toolkit will receive up to \$300.00 in compensation over 6 months of study participation. Families will be compensated \$25 for each baseline visit (\$50 total) and \$50 for each of the follow-up dental visits at 3 months and 6 months. In addition, \$75 for each completed follow-up dental visit will be reserved for families and paid out at the completion of the final 6-month follow-up visit (an additional \$150).

Differences in compensation are based upon the required time and commitment for study participation.

Reimbursement

You will not be reimbursed for any out of pocket expenses, such as parking or transportation fees.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

You will be responsible for any routine payments associated with the clinical care provided by the dental office. There are no additional costs to you for participation in this study.

WHAT HAPPENS IF I WANT TO STOP TAKING PART IN THIS STUDY?

You are free to withdraw from this study at any time. **If you decide to withdraw from this study, you should notify the research team immediately.** The research team may also end your participation in this study if you do not follow instructions, miss scheduled visits, the study sponsor decides to stop the study or your safety and welfare are at risk.

For example, in the event that your child experiences a need for emergency dental treatment, you may need to be withdrawn from the study, even if you would like to continue. The research team will make this decision and let you know if it is not possible for you to continue. The decision may be made to protect your safety and welfare.

If you elect to withdraw or are withdrawn from this research study, you may choose to terminate the continued use or disclosure of your protected health information (PHI) for research purposes. The request to end the use or disclosure of your PHI should be made in writing.

HOW WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT?

Subject Identifiable Data

Some identifiable information collected about you will be kept with the research data. We will minimize collection of personally identifiable information. However, we will collect some information such as date of birth in order to calculate precisely the age of participating children and family members.

Data Storage

Research data will be maintained in paper format in a secure location at UCI. Only authorized individuals will have access to it. Research data will also be stored electronically on a secure computer/network in an encrypted file.

Research data will also be stored electronically on a password-protected database managed by the Massachusetts General Hospital Data Coordinating Center. Only authorized individuals will have access to it.

Research data will be de-identified through use of a unique identification number generated by Massachusetts General Hospital Data Coordinating Center for each child participating in Autism Treatment Network / Autism Intervention Research Network on Physical Health (ATN / AIR-P) sponsored

projects. If your child participates in other ATN / AIR-P sponsored projects, the same identification number will be used across studies.

The video recordings that can identify you will also be stored in a secure location at UCI and at CSUF. The recordings will be retained with the other research data.

Data Retention

The researchers intend to keep the research data for seven years after all children enrolled in the study reach the age of majority (age 18 in California).

WHO WILL HAVE ACCESS TO MY STUDY DATA?

The research team, including authorized personnel at UCI, Healthy Smiles for Kids of Orange County, and California State University, Fullerton, as well as the study sponsor, the Massachusetts General Hospital clinical coordinating center and data coordinating center, our collaborating site at Nationwide Children's Hospital, and regulatory entities may have access to your study records to protect your safety and welfare.

Any information derived from this research project that personally identifies you will not be released or disclosed by these entities without your separate written consent, except as specifically required by law. Publications and/or presentations resulting from this study will not include identifiable information about you.

While the research team will make every effort to keep your personal information confidential, it is possible that an unauthorized person might see it. We cannot guarantee total privacy.

ClinicalTrials.gov is a Web site that provides information about clinical trials. 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.

Investigator Financial Conflict of Interest

No one on the study team has a disclosable financial interest related to this research project.

Request for Data for Future Use

This is a request for donation of your data for research. Please read each sentence below and think about your choice. After reading each sentence, put your initials in either the "Yes" or "No" box. If you have any questions about this request for data, please talk to the researchers.

1. UCI researchers may contact me in the future to ask me to take part in other research studies.

YES	NO
-----	----

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?

If you have any comments, concerns, or questions regarding the conduct of this research, please contact the research team listed at the top of this form.

A 24-hour number is also listed on the top of this form to report any health concerns or unanticipated problems you may experience after normal hours or on weekends.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any suggestions, problems or concerns you may have about the study, please contact UCI's Office of Research by phone, (949) 824-6068 or (949) 824-2125, by e-mail at IRB@research.uci.edu or at 141 Innovation Drive, Suite 250, Irvine, CA 92697.

HOW DO I AGREE TO PARTICIPATE IN THIS STUDY?

You should not sign and date this consent form until all of your questions about this study have been answered by a member of the research team listed at the top of this form. You will be given a copy of this signed and dated consent form, and the attached "Experimental Subject's Bill of Rights" to keep.

Participation in this study is voluntary. You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your future relationship with UCI or your quality of care at the UCI Medical Center or our partner dental site, Healthy Smiles for Kids of Orange County.

If, during the course of this study, significant new information becomes available that may relate to your willingness to continue to participate, this information will be provided to you by the research team listed at the top of the form.

Your signature below indicates you have read the information in this consent form and have had a chance to ask any questions you have about this study.

Note: If the research described in this form involves your protected health information (PHI), you will be asked to sign separate UC HIPAA Research Authorization form for the use of your PHI.

I agree to participate in the study.

Subject Signature

Date

Printed Name of Subject

Legally Authorized Representative/Guardian Signature

Date

Printed Name of Legally Authorized Representative/Guardian

Relationship to Subject

Legally Authorized Representative/Guardian Signature

Date

Printed Name of Legally Authorized Representative/Guardian

Relationship to Subject

Signature of Person Obtaining Informed Consent
(Individual must be listed on Page 1 of this consent)

Date

Printed Name of Person Obtaining Informed Consent

A witness signature is required on this consent form only if: (Researchers: check which one applies)

- ☐ Consent is obtained from the subject via the Short Form process, as approved by the IRB.
- ☐ The subject has decision-making capacity, but cannot read, write, talk or is blind.
- ☐ The subject's guardian/legally authorized representative (LAR) cannot read, write, talk or is blind.
- ☐ The IRB specifically mandated a witness signature for this study (e.g., high risk and/or invasive research procedures).

Note: The witness must be impartial (i.e. not a member of the subject's family, not a member of the study team).

For the witness:

I confirm that the information in this consent form was accurately explained to and understood by the subject or legally authorized representative and that informed consent was given freely.

Witness Signature

Date

(If no witness signature is required, this witness signature section of the consent form may be left blank).

Printed Name of Witness

UNIVERSITY OF CALIFORNIA, IRVINE
Experimental Subject's Bill of Rights

The rights listed below are the right of every individual asked to participate in a research study. You have the right:

1. To be told about the nature and purpose of the study.
2. To be told about the procedures to be followed in the research study, and whether any of the drugs, devices, or procedures is different from what would be used in standard practice.
3. To receive a description of any side effects, discomforts, or risks that you can reasonably expect to occur during the study.
4. To be told of any benefits that you may reasonably expect from the participation in the study, if applicable.
5. To receive a description of any alternative procedures, drugs, or devices that might be helpful, and their risks and benefits compared to the proposed procedures, drugs or devices.
6. To be told of what sort of medical treatment, if any, will be available if any complications should arise.
7. To be given a chance to ask any questions concerning the research study both before agreeing to participate and at any time during the course of the study.
8. To refuse to participate in the research study. Participation is voluntary. You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your right to receive the care you would receive if you were not in the experiment.
9. To receive a copy of the signed and dated written consent form and a copy of this form.
10. To be given the opportunity to freely decide whether or not to consent to the research study without any force, coercion, or undue influence.

If you have any concerns or questions regarding the research study you should contact the research team listed at the top of the consent form.

If you are unable to reach a member of the research team and have general questions, or you have concerns or complaints about the research study, research team, or questions about your rights as a research subject, please contact the UCI's Human Research Protections unit in the Office of Research by calling (949) 824-6068 or (949) 824-2125 Monday – Friday, 8 am – 5 pm; or by e-mail at IRB@research.uci.edu; or by writing us at 141 Innovation Drive, Suite 250, Irvine, CA 92697.