

**UNIVERSITY OF CALIFORNIA, IRVINE
ASSENT TO BE IN A HUMAN RESEARCH STUDY**

The Center for Autism & Neurodevelopmental Disorders Research Recruitment Database

Participating in this study is totally voluntary. Please read about the study below. Feel free to ask questions about anything that you do not understand before deciding if you want to be in the study. A researcher listed below will be around to answer your questions.

RESEARCH TEAM

Lead Researcher:

Jean Gehricke, PhD
Department of Pediatrics

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(949) 267-0484

Other Researchers

Joseph Donnelly, MD
Robin Steinberg-Epstein, MD
Jeanne Anne Carriere, PhD
Anna Laakman, MEd
Lisa Tully, PhD
Rachel Fenning, PhD
Michele Ocen, PhD, BCBA
Caroline Grantz, PhD
Thusa Sabapathy, MD
Marc Lerner, MD
Jose Lopez-Lizarraga, MD

Elyse Schoenwald, MSN, RN
Kristen Joyner, PsyD
Maureen Dillon, LCSW
Marlene Cuevas, MSW
Kim Dieu, EdS
Jennifer Phan
Sharina Dyan Alejo
Meghan Dawson
Bethany Peralta
Elizabeth Rojas
Zulema Gil

Maricela Ortiz
Natalye Pacheco
Kristine Alcaez
Patty Soto
Jennifer Gutierrez
Barbara Soria
Marilyn Nunez
Pedro Velasco
Roxanne Cornejo

The Center for Autism & Neurodevelopmental Disorders
(949) 267-0454

STUDY LOCATIONS:

University of California, Irvine (UCI) - The Center for Autism & Neurodevelopmental Disorders (CAND),
Santa Ana, CA

WHY ARE YOU HERE?

The doctors and their helpers want to tell you about a research study and ask if you want to participate in 4 different ways:

- 1) They want to ask you if it is ok to collect and save information about you into an information bank called a database
- 2) They want to ask you whether it is ok for them to share information about you with the Autism Treatment Network (ATN) and enter data into their database. The Autism Treatment Network is a group of hospitals, doctors, researchers, and families at 14 locations across the United States and Canada. They are working together to find the best ways to help people affected by autism.
- 3) They want to ask you whether it is ok for them to share information about you with the Autism Learning Network and enter data into their database. The Autism Learning Network is a new project created by the ATN.

- 4) They want to ask you whether it is ok for them to share information about you with the ATN Family Navigation Study and enter data into their database. The Family Navigation Study is a new project created by the ATN.
- 5) They want to know if you can give a saliva sample to see if there is any useful genetic information in saliva that will help us help other kids.
- 6) They also want to ask you whether they can contact your parent(s)/guardian(s) to let you know about other research studies you might want to join.

WHY ARE THEY DOING THIS STUDY?

The doctors and their helpers are doing this study to learn more about the causes, outcomes, and best treatments. They also want to help other researchers to find participants.

WHAT WILL HAPPEN TO YOU?

Your visits at The Center will be no different whether you choose to or not to participate in this study. If you agree, the information you provide will be entered and stored into a database. If you agree, the information you provide will be entered into the ATN Registry database and/or the Autism Learning Network database. This information will not include your name or other information that identifies you. You will be asked to put a cotton swab in your mouth to collect your saliva. If you give your permission, your parents may later be contacted by phone, mail, or email about research studies.

WILL THE STUDY HURT?

This study does not hurt. We will only be collecting information about you and storing it. Your visits at The Center will be no different if you choose to or choose not to participate. If you provide a saliva sample, the soft swab that is used may feel funny in your mouth or may cause your mouth to go dry. That feeling should only last a few minutes.

WILL YOU GET BETTER IF YOU ARE IN THE STUDY?

This study does not affect whether you will get better or not. The doctors/researchers will not be doing anything that will change your treatment/care. Your visits at The Center will be no different if you choose to or choose not to participate.

WHAT IF YOU HAVE ANY QUESTIONS?

You can ask questions any time. You can ask now or you can ask later. You can talk to the doctors/researchers, your mom and dad, or you can talk to someone else.

DO YOU HAVE TO BE IN THE STUDY?

You do not have to be in the study. No one will be mad at you if you don't want to do this. If you don't want to be in this study, you just have to tell the doctors/researchers. If you want to be in the study, you just have to tell them. You can say yes now and change your mind later. It is up to you to decide.

- I agree to have information about me saved and entered into a database.***
- I agree to have information about me shared with the Autism Treatment Network (ATN) and entered into a database.***
- I agree to have information about me shared with the Autism Learning Network database.***
- I agree to have information about me shared with the Family Navigation Study database.***

- I agree to give a saliva sample for the microRNA diagnostic test.***
- I agree for my parent(s)/guardian(s) to be contacted about research studies that I might want to join.***

Signature of Minor

Age

Date

Printed Name of Minor

Signature of Researcher

Date

Printed Name of Researcher

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

- The subject has decision-making capacity, but cannot read, write, talk or is blind.
- The IRB specifically mandated a witness signature for this study.

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 assent form was accurately explained to and understood by the subject or legally authorized representative and that informed assent was given freely.

Witness Signature

Date

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

Printed Name of Witness