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

The Center for Autism & Neurodevelopmental Disorders Research Recruitment Database

You are being asked to participate in a research study. Participation is completely voluntary. 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."

RESEARCH TEAM

Lead Researcher

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Other Researchers

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Jose Lopez-Lizarraga, MD	Zulema Gil	

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 IS THIS RESEARCH STUDY BEING DONE?

The purpose of this research study is to collect consent from families to participate in a research database, to participate in the ATN Registry, to participate in the Autism Learning Network Database (ALND), and to be contacted about future research studies in autism and neurodevelopmental disorders.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

This study will enroll approximately 5000 participants. All study procedures will be done at the Center for Autism and Neurodevelopmental Disorders (CAND).

Inclusion Requirements
Inclusion Criteria for Clinical Database:
- All children, adolescents, and young adults who receive treatment at CAND.

Inclusion Criteria for ATN:
- Children between the ages of 2-17 years, with a diagnosis of an ASD, who receive ongoing care at CAND.

Inclusion Criteria for ALND:
- Children between the ages of 3-12 years, 6 months, with a diagnosis of an ASD, who receive ongoing care at CAND.

Inclusion Criteria for microRNA Diagnostic Test:
- Children between the ages of 2 – 13 years.
- Meet criteria for an ASD according to the DSM-5

Inclusion Criteria for Family Navigation Study
- Children under the age of 12 years
- Diagnosed/assessed at CAND within the prior 3 months with an autism spectrum disorder

Exclusion Criteria
Exclusion Criteria for ATN Registry, ALND, and Family Navigation Study:
-Recruitment is limited to English Speakers

Exclusion Criteria for microRNA Diagnostic Test:
-Confounding neurological (i.e. cerebral palsy, epilepsy), sensory (i.e. sensory or visual impairments) or mental disorders (i.e. obsessive compulsive disorders, attention deficit hyper activity disorder). Participants with a history of pre-term birth or mental retardation will not be eligible.

HOW LONG WILL THE STUDY GO ON?
This study may be completed in one visit. Should you choose to participate, you will be asked to complete a patient history form. Should you choose to participate in the ATN Registry, the Autism Learning Network Database, and/or the AS ATN Family Navigation Study you may be asked to complete additional questionnaires. Should you choose to participate in the Family Navigation Study, you may be asked to participate in a post study phone interview conducted by our study sponsor, MGH. You will also be asked whether you give consent to be contacted about future research studies.

WHAT PROCEDURES ARE INVOLVED WITH THIS STUDY?
You are being asked to take part in this study because you or a family member has come to CAND for diagnosis, treatment or follow-up.

All individuals and their families who come to CAND for diagnostic assessment, treatment, or follow-up will be asked to take part in this study.

We are asking for your permission to collect contact information, the diagnosis of your child, and information extracted from various assessments and questionnaires administered clinically and/or from other research studies, such as the ATN Dental Study or the Physical Exercise study to Reduce Anxiety in Children with ASD (PETRA) to store in a research recruitment database We will also be collecting a saliva sample from your child to test the link between genetic material (i.e., microRNA) and ASD.

As the Center was recognized as an Autism Speaks Autism Treatment Network (AS ATN) site in 2014, we are also asking for your permission to share de-identified data to the ATN Registry Database, the

Autism Learning Network Database, and the AS ATN Family Navigation Study Database. The Autism Treatment Network is a network of hospitals, physicians, researchers, and families at 13 locations across the United States and Canada. The network is dedicated to improving the health and healthcare of children and youth with ASD by providing comprehensive, multidisciplinary care within the community through the study of empirical data. The Autism Learning Network is an effort of collaboration between the AS ATN and the Autism Intervention Research Network for Physical Health (ATN/AIR-P). The AS ATN Family Navigation Study is an effort to assess the effectiveness of family navigation for parent and family empowerment and activation. The data we are asking your permission to share will help our site and those in the network to develop the most effective approach to care for children and adolescents affected by autism.

For the AS ATN Registry, ALND, and AS ATN Family Navigation Study Database you may choose to complete assessments and questionnaires electronically. This would involve providing your email address to create an account for you. Once the account is created, you will create your own personal password to manage your account. Your email will also be used to notify/remind you of required assessments. If you do not choose to use these electronic data collection (EDC) systems, you may still participate in these projects by completing paper forms, which are then entered into the EDC system by our research staff.

We are also asking for your permission to contact you about possible participation in future research projects. We will use information gathered from the patient history form you complete and we will obtain information about your child's diagnosis in order to screen for his or her eligibility for future research studies prior to contacting you. Should you choose to participate, you will be contacted by CAND staff and informed about current research projects on autism and/or other neurodevelopmental disorders.

You will then have the opportunity to contact these studies for more information and to enroll in the study. Your decision to participate in any research project is voluntary and you can decide not to participate in any of the future research projects that are presented to you.

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

This study involves no more than 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. The saliva collection for the microRNA diagnostic test involves placing a soft swab inside the bottom of the child's mouth. The swabs have no flavor and thus should not cause any pain or unpleasantness. There might a slight sensation of dryness in the mouth once the saliva has been collected. Although genetic information will be collected, this information will never be placed in the participant's medical record. All samples sent to SUNY Upstate will be de-identified, ensuring no breach in confidentiality.

ARE THERE BENEFITS TO PARTICIPATING IN THIS STUDY?

Participant Benefits

You will not directly benefit from participation in this study. Participation in this research study will allow us to inform you about future research studies.

However, if you choose to participate in any of the future research studies you are contacted about, the data collected from those studies is expected to help researchers and clinicians learn more about autism.

Benefits to Others or Society

This study has no direct benefits to others or society. However, if you choose to participate in any of the future research studies you are contacted about, the data collected from those studies is expected to help researchers and clinicians learn more about autism.

WHAT OTHER CHOICES DO I HAVE IF I DON'T WANT TO PARTICIPATE?
Participation is voluntary. An alternative is to not participate in this research study. If you choose not to participate, your routine medical care will not be affected.

WILL I BE PAID FOR TAKING PART IN THIS STUDY?
Compensation
Compensation of $25.00 will be given to participants of the microRNA diagnostic test. However, there is no compensation for the remainder components of the study.

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?
There is no cost 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.

If you withdraw or are removed from the study, the researcher may ask you to inform us. Your decision to withdraw from the study will not affect in any way your medical care and/or benefits.

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. Data that has already been collected and submitted will remain in the database.

HOW WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT?
Subject Identifiable Data
All identifiable information collected about you will be kept with the research data. For this study your identifiable information is important to allow us to contact you about future research projects.

Data Storage
The clinic database is encrypted and its storage and maintenance procedures have been determined by UC Irvine Health Information Systems to meet HIPAA, confidentiality, privacy, and security standards. Only authorized individuals who have been listed on this protocol will have access to this database. Users will be granted permissions only to sectors of the database required for their job function. The data in the database will be kept indefinitely and a participant will be considered as active until they choose to withdraw from the study.

The ATN Registry, ALND, and AS ATN Family Navigation Study use secure Internet data capture systems to collect and store data. All data is de-identified prior to entry by creating both a unique AS ATN identification number and a global unique identifier (GUID). All data will only be referred to by these numbers and only The Center's staff listed on this protocol will have access to the identifying information.

If you participate in the salivary microRNA diagnostic test, data will be stored on a secured, HIPAA compliant server at Motion Intelligence and SUNY Upstate lab. The saliva samples will be stored without any identifiers (such as your child's name or medical record number); if SUNY distributes the child's

samples to other researchers or institutions, the samples will be labeled with a research code without identifiers so that your child cannot be identified.

Data Retention
The researchers intend to keep the research data indefinitely.

WHO WILL HAVE ACCESS TO MY STUDY DATA?
The research team, authorized UCI personnel, and regulatory entities such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP), 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. Research records provided to authorized, non-UCI entities will not contain identifiable information about you. 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

Data shared with the ATN Registry database, Autism Learning Network database, and AS ATN Family Navigation Study database will be submitted to the ATN through secure internet data capture systems. Data is de-identified and will be kept anonymous. The ATN Registry is managed by the Data Coordinating Center (DCC) at Massachusetts General Hospital in Boston, MA and Cincinnati Children's Hospital Medical Center (CCHMC). The AS ATN may work with other federally or privately supported groups that study ASDs to exchange information and facilitate research in this area. All such groups are required by law to protect participants' confidential information. The information obtained as part of the Registry and ALND may be published in scientific journals or presented at scientific meetings; however all participants' identities will be kept strictly confidential.

Duet Health will host the smart-phone app and a web-based system for parental data collection for the ALND study. Parents will complete study questionnaires through a secure log-in. No personal identifiable information will be collected or shared. Data will be securely transferred from the app to and stored at CCHMC.

Motion Intelligence, Inc will be the web-portal host for the Autism Health Study Questionnaire for the microRNA study. SUNY Upstate will have access to this questionnaire data. No personal identifiable information will be collected or shared. Parents can complete this questionnaire through a secure log-in at the time of their child's saliva sample appointment.

ARE THERE OTHER ISSUES TO CONSIDER IN DECIDING WHETHER TO PARTICIPATE IN THIS STUDY?
Use of Specimens
Any specimens (e.g., saliva) obtained for the purposes of this study will be provided to SUNY Upstate. SUNY lab members will not have access to the original subject-identifiable information. Once you provide the specimens, you may not have access to them. Use of the specimens could result in discoveries that could become the basis for new products or therapeutic agents. In some instances, these discoveries may be of potential commercial value. You will not receive any money or other benefits derived from such a product.

Genetics
In the event of an unexpected breach of confidentiality, a federal law called the Genetic Information Non-Discrimination Act (GINA) will help protect you from health insurance or employment discrimination based on genetic information obtained about you. In California, state law (CalGINA) requires that employers with 5 or more employees may not use your genetic information, obtained from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment. However, these laws do not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

If you would like more information about the federal GINA law go to:
http://www.genome.gov/Pages/PolicyEthics/GeneticDiscrimination/GINAInfoDoc.pdf or CalGINA:
http://www.leginfo.ca.gov/pub/11-12/bill/sen/sb_0551-0600/sb_559_bill_20110906_chaptered.pdf

Investigator Financial Conflict of Interest
No one on the study team has a disclosable financial interest related to this research project.

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.

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.

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

I agree to participate in the study in the following way(s). Please check all that apply.

☐ ***I agree to have the information I provide on the Patient History Form entered as data into a research database.***

☐ ***I agree to have my de-identified data entered into the AS ATN Registry/Callback study database.***

☐ ***I agree to have my de-identified data entered into the Autism Learning Network database.***

☐ ***I agree to have my de-identified data entered into the AS ATN Family Navigation Study database.***

☐ ***I agree to provide a saliva sample for use in the microRNA diagnostic test.***

☐ ***I agree to be contacted about opportunities to participate in research studies.***

☐ ***I agree to provide my email address to create an account on an electronic data collection (EDC) system so that I can complete assessments/questionnaires electronically. I understand that I will also receive email notifications to alert/remind me to complete assessments.***

_____ _____
Subject Signature **Date**

_____
Printed Name of Subject

_____ _____
Legally Authorized Representative/Guardian Signature ***Date***

_____ _____

Printed Name of Legally Authorized Representative/Guardian ***Relationship to Subject***

_____ _____

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

_____

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.