

**UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN A RESEARCH STUDY**

Study Title: Utility of nasal nitric oxide as a biomarker of ASD and epilepsy

**Parental Consent
For Subjects 2-17 years old**

Research Project Director:	Helen Willsey, Ph.D., Assistant Professor UCSF, 1651 Fourth St, 5 th floor, San Francisco, CA. Phone: 615-429-7773
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Study Coordinator:	Juan Arbelaez, Staff Research Associate UCSF, 1651 Fourth St, 5 th floor, San Francisco, CA.
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This is a research study where your study director, Helen Willsey, PhD, will explain the study to you.

Research studies include only people who choose to take part. Please take your time to make your decision about your child participating. You may discuss your decision with your family and friends and with your child’s health care team. If you have any questions, you may ask the study director.

Your child is being asked to take part in this study because they are between 2 and 17 years old and have a genetic variant associated with autism spectrum disorder (ASD) and/or epilepsy OR they are a direct relative of someone who does have such a genetic variant. If you decide to have your child participate, they will perform a breathing test called “nasal nitric oxide”.

Why is this study being done?

The purpose of this study is to learn more about ASD and epilepsy. We want to evaluate a testing method, called nasal nitric oxide testing, to see if it can serve as a measurement (also known as a biomarker) to detect these disorders. Nasal nitric oxide is a test to detect defects in a cellular structure called cilia, which our research has shown to be relevant to ASD and epilepsy genetics. Therefore, we want to determine whether this test is relevant to ASD and epilepsy as well.

This study is unfunded and has no sponsor. Departmental funds will be used to cover any costs to undertake this study at UCSF. In order to do the nitric oxide testing, a device called NIOX Vero will be used. The NIOX Vero is an investigational device, which means it has not been FDA approved for commercial clinical use and is labeled for research use.

How many people will take part in this study?

About 200 children, adolescents, and adults will be asked to take part in this study. Only UCSF is conducting this study.

What will happen if my child takes part in this research study?

If you and your child choose to participate in this research study, the following will happen.

- We will ask you for information about your child's genetic variant (if they have one), their name, age, sex, and your contact information. This information will be entered into a secure online database known as REDCap. Your child will be given a de-identified subject ID number.
- Within REDCap, this clinical and personal information, along with the results of the test performed during this study, will be stored. Once information is provided, we will not be able to remove as this a FDA-regulated study.
- Your child's nasal nitric oxide levels and other information recorded in the REDCap database about them may be published in peer-reviewed journals. To protect your child's privacy, we will not release their name. You and your child will not receive any benefit as a result of the tests done with their information. These tests may help us learn more about the causes, risks, and treatments for ASD and other health problems.
- Your child's information may be used to make new products or tests. These may have value and may be developed and owned by the study staff, UCSF, and/or others. If this happens, there are no plans to provide money to you.
- Your child will undergo nasal nitric oxide testing. The results of the nasal nitric oxide test will be disclosed to you for reference and share with your child's healthcare provider(s) if desired. The nasal nitric oxide test will take place at the UCSF Mission Bay campus. This test does not involve any sedation or collection of biological specimens (such as blood). It is a non-invasive test that measures the nitric oxide (a type of gas) level in the nasal passage. The test is done by placing a small foam tube in your child's nose at a depth of about 11 mm, or less than half an inch. The nitric oxide level is measured as your child breathes out normally. This research test takes about 3 minutes and is done in the dry lab space of our research laboratory in an office.
- **Study location:** All study procedures will be done at UCSF Mission Bay campus in the Weill Institute for Neurosciences building.

How long will my child be in the study?

The total time commitment for participating in this study is about 15 minutes.

Can my child stop being in the study?

Yes. You and your child can decide to stop at any time. Tell the study director if you are thinking about stopping or deciding to stop. If you withdraw from the study, any data we have already collected about you will remain part of the study records.

The study director may stop your child from taking part in this study at any time if she believes it is in their best interest, if you or your child do not follow the study rules, or if the study is stopped.

What side effects or risks can my child expect from being in the study?

Your child may have side effects while on the study. Many side effects go away soon after your child stops the nasal nitric oxide testing. You should talk to your study director about any side effects your child experiences while taking part in the study.

Risks and side effects related to the nasal nitric oxide testing include nasal discomfort from the foam tube being placed in the nostril.

Unknown Risks: There may be side effects that no one knows about yet. The researchers will let you know if they learn anything that might make you change your mind about your child participating in the study.

For more information about risks and side effects, ask your study director.

Are there benefits to taking part in the study?

There will be no direct benefit to you or your child from participating in this study. However, this study will help researchers learn more about ASD and epilepsy. Participation in this research study may allow us to continue to learn about these disorders and develop biomarkers.

What other choices does my child have if they do not take part in this study?

You and your child are free to choose not to participate in the study. If you decide not to take part in this study, there will be no penalty to your child. Your child will not lose any of their regular benefits, and will still get care the way your child usually does.

How will my child's information be used?

Researchers will use your child's information to conduct this study. Once the study is done using your child's information, we may use the information for future research studies or share it with other researchers so they can use it for other studies in the future. We will not share your child's name or any other personal information. We cannot guarantee that this will prevent future

researchers from determining who your child is. We will not ask you for additional permission to share this de-identified information.

How will information about my child be kept confidential?

Participation in research involves some loss of privacy. We will do our best to make sure that information about your child is kept confidential, but we cannot guarantee total privacy. Study tests that are performed by research labs, and information gathered directly from you by the researchers will be part of your child's research records but will not be added to your child's medical record. Your child's personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your child's name and other personal information will not be used.

Authorized representatives from the following organizations may review your child's research data for the purpose of monitoring or managing the conduct of this study:

- Representatives of the University of California
- Representatives of the Food & Drug Administration (FDA)

Are there any costs to me for my child taking part in this study?

No. The sponsor has agreed to pay for all procedures associated with this research study; you or your child's insurer will not be billed.

Will my child be paid for taking part in this study?

You and your child will not be paid for taking part in this study.

What happens if my child is injured because they took part in this study?

It is important that you tell your study director, Helen Willsey, PhD, if you feel that your child has been injured because of taking part in this study. You can tell her in person or call her at 615-429-7773.

Treatment and Compensation for Injury: If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California, depending on a number of factors. The University does not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Institutional Review Board at 415- 476-1814.

What are my child's rights if they take part in this study?

Taking part in this study is your choice, and your child's choice. You may choose either to have your child take part or not to take part in the study. If you decide to have your child take part in this study, your child may leave the study at any time. No matter what decision you make, there will be no penalty to your child and they will not lose any of their regular benefits. Leaving the study will not affect your child's medical care. Your child can still get medical care from our institution.

We will tell you about new information or changes in the study that may affect your child's health or your willingness to have your child continue in the study.

In the case of injury resulting to your child from this study, you do not lose any legal rights to seek payment by signing this form.

Who can answer my questions about the study?

You can talk to the study director about any questions, concerns, or complaints you have about this study. Contact your study director, Helen Willsey, PhD, at 615-429-7773.

If you wish to ask questions about the study or your child's rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the office of the Institutional Review Board at 415-476-1814.

CONSENT

You have been given copies of this consent form and the Experimental Subject's Bill of Rights to keep.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled.

If you wish your child to participate in this study, you should sign below.

The person being considered for this study is unable to consent for himself/herself because he/she is a minor. By signing below, you are giving your permission for your child to be included in this study.

Date

Parent or Legal Guardian

Date

Person Obtaining Consent

Date

Witness – Only required if the participant is a non-English speaker