



University of California, San Diego  
Parent Consent for Child to Act as a Research Subject

**The UCSD Newborn Screening-Autism Risk Study—Phase 2**

***Introduction***

Dr. Naviaux and his colleagues are conducting this research and asking for your consent to participate/allow your child to participate. This section provides a summary of important information. The rest of the form provides additional details.

- Research is voluntary - whether or not you agree/agree to allow your child to join is your decision. You can discuss your decision with others (such as family, friends or another physician).
- You can say yes but change your mind later.
- If you say no, we will not hold your decision against you or your child.
- Your decision will not affect you or your child's health care or any other benefits you or your child may be entitled to.
- You can say no even if the person inviting your child is part of your child's healthcare team.
- Please ask questions or mention concerns before, during or after the research.

The purpose of this study is to see if a new test for the measurement of about 1000 chemicals in the dried blood spots that were collected at birth and stored at the state health department can be used to predict the risk of a future diagnosis of Autism Spectrum Disorder (ASD). **No new blood tests or visits to your doctor are needed.** Any child or parent born in California may be eligible. Participation in the study will not benefit you/your child directly. However, if the new test is found to predict the risk of a future diagnosis of ASD, there may be a significant benefit to society.

If you agree to participate/allow your child to participate, there will be three steps you will need to complete. A brief description of the steps is provided below and more detailed information is provided later in this form:

**Step #1—Online:** Review study information and submit a signed study consent form.

**Step #2—Online:** Complete an online screening questionnaire that will take about 5 minutes to complete. Study staff will then match your child with their standard newborn screening results and stored dried blood spots at the California Biobank Program (CBP) in Sacramento.

**Step #3—Online:** Complete a study questionnaire of about 50 questions that will take about 20 minutes to complete. We must be able to match your child to their screening results/dried blood spots for you to move to this step.

Since this study does not involve any new blood draws or interventions, or any direct medical contact, there is no risk of any physical pain or injury as part of this study. The most serious risk of the study is a potential loss of your/your child's confidentiality. Because this is a research study, there may be some unknown risks that are currently unforeseeable. You and your child will be informed of any significant new findings.

Additional, detailed information about this research is provided below. Please feel free to ask questions before signing this consent.

***Why has your child been asked to participate, how was your child selected, and what is the approximate number of participants in the study?***

You and your child have been asked to participate because either your child has been diagnosed with Autism Spectrum Disorder (ASD), or does not have ASD and is a healthy child without any developmental, behavioral, or medical issues. Boys and girls who were born in California and are now 3-10 years old are eligible for this study. Approximately 175-200 children with ASD and 175-200 healthy children ages 3-10 years will participate in this study. A total of about 400 children will be enrolled in this study. All participants in this study must enroll by following the instructions listed on Dr. Naviaux's website: <http://naviauxlab.ucsd.edu/study/>.

***What will happen to your child in this study and which procedures are standard of care and which are experimental?***

This study does not require any medical visits or new blood draws from your child. After completing the screening and study questionnaires, and giving Dr. Naviaux permission to request your child's newborn screening results and a sample of the dried blood spots collected at birth, no further study procedures are required.

If you agree/agree for your child to be in this study and we are able to match your child with their screening results/dried blood spots collected at birth, the following is a more detailed description of what will happen:

**Step #1—Online:** Please go to the Naviaux Lab website at: <http://naviauxlab.ucsd.edu/study/>. On the website, please review the study criteria to be sure your child qualifies and download 3 files: 1) a copy of this parent consent/permission, 2) the recruitment brochure, and 3) the Experimental Subject's Bill of Rights. If you have any questions about the study, please call the study coordinator, Jane, directly at: 619-933-1408. Once you have reviewed these documents and have had your questions answered, or if you have no questions, please sign this consent/permission and send a scanned electronic copy or photo to the study coordinator, Dr. Jane C. Naviaux, MD, PhD at: [jnaviaux@ucsd.edu](mailto:jnaviaux@ucsd.edu). Step #1 can take from 5-30 minutes, depending on your questions.

**Step #2—Online:** Once you have submitted a copy of your signed informed consent/permission, you will be sent a secure computer link by email to fill out an online screening questionnaire that asks about the study inclusion and exclusion, and some basic information; your child’s and the child’s mother’s name, date of birth, and hospital of birth. It will take about 5 minutes to complete. The screening questionnaire will allow us to match your child with their standard newborn screening results and stored dried blood spots at the California Biobank Program (CBP) in Sacramento. Not all children will qualify for the study because sometimes we will not be able to match a child to their screening results/stored dried blood spots. It will take Dr. Naviaux’s team about 2 months to match your child with their CBP records. Once we have made a match, we will contact you again to invite you to fill out the study questionnaire (Step #3 below).

**Step #3—Online:** After your child has been matched to their screening results/dried blood spots you will be contacted by email and given a secure computer link to complete a study questionnaire consisting of about 50 questions about your pregnancy, labor and delivery, and your child’s health and infection history, antibiotic use, developmental milestones, and the health history of other siblings, mother’s and father’s health, and the health of your relatives. It will take about 20 minutes to complete. Some of the questions will apply only to children with ASD. If your child is a typically developing participant, the ASD-related questions will not appear in the questionnaire. The study questionnaire will help us interpret the results of the newborn screenings and the new test we will study.

After you have signed this parent consent/permission and completed the 2 questionnaires, Dr. Naviaux’s team will request a sample of the dried blood spots collected at birth, and the results of the California newborn screening tests that were done when you were/your child was born.

***How much time will each study procedure take and how long will the study last?***

Your/your child’s participation in this study will take about 30 minutes of your time to sign the consent, and complete the 2 questionnaires. Because it will take about 2 months to match each child with their stored newborn dried blood spots, the minimum time between enrollment and completion is 2 months. After enrolling all 400 children planned in this study, it will take Dr. Naviaux about 2 years to complete the study.

***What happens if you change your mind about participating/allowing your child to participate?***

If you decide that you no longer wish to continue in this study, you will be requested to contact the Study Coordinator Dr. Jane C. Naviaux by email at [jnaviaux@ucsd.edu](mailto:jnaviaux@ucsd.edu) and request to be dropped from the study. Data collected up until withdrawal will remain in the study file. If you wish, you may also request that any remaining dried blood spots stored in Dr. Naviaux’s lab be destroyed.



You and your child will be told if any important new information is found during the course of this study that may affect your wanting to continue/allow your child to continue.

***Can you/your child be withdrawn from the study without your consent?***

You/your child may be withdrawn from the study if the information you provided in the screening questionnaire cannot be matched to dried blood spots/standard newborn screening results collected and stored at birth in California. You/your child may also be withdrawn from the study if you do not follow the instructions given to you by the study personnel.

***Will you be compensated for participating in this study?***

In compensation for your time, you will receive a \$40 Amazon eGift certificate by email after completing the study questionnaire in Step #3 of this study. No compensation will be provided if you complete the screening questionnaire but we are unable to match your child to the California Biobank Program (CBP) records. It may take 2 months or more after completing the screening questionnaire to determine if there is a match.

***Are there any costs associated with participating in this study?***

There will be no cost to you or your child for participating in this study.

***What if you/your child is injured as a direct result of being in this study?***

Since this study does not involve an intervention, there is no risk of physical injury to you or your child. However, if you/your child is injured as a direct result of participation in this research, the University of California will provide any medical care you/your child needs to treat those injuries. The University will not provide any other form of compensation to you if you/your child is injured. You or your child may call the Human Research Protections Program Office at 858-246-HRPP (858-246-4777) for more information about this, to inquire about your rights as a research subject or to report research-related problems.

***What about your/your child's confidentiality?***

Research records will be kept confidential to the extent allowed by law. All identifying study material/information will be stored in a locked file cabinet or a password protected computer with an encrypted hard drive in Dr. Naviaux's office. Study records will be coded with unique subject identifying (ID) numbers. The unique subject ID numbers will be linked to identifiable information in a document that is kept separate from study data/files.

An electronic image file of the informed consent document you signed will be stored on a password protected and encrypted hard drive on a computer in Dr. Naviaux's office and any paper hard copies of consents are stored in a locked file cabinet. The results of the online questionnaires and dried blood spot testing are kept on a secure server maintained by UCSD Information Security. The dried blood spot testing results are kept on a password protected and encrypted hard drive at UCSD. Only Naviaux Lab

personnel directly involved with this study will have access to the electronic records for this study.

The physical dried blood spots will be labelled with subject IDs and kept in a locked - 80°C freezer in Dr. Naviaux’s lab. Research records may be reviewed by the UCSD Institutional Review Board. No DNA testing will be performed as part of this study.

Personal identifiers might be removed from the information or biospecimens collected as part of the research. After such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent/permission.

Biospecimens (bloodspots) collected from your child for this study and/or information obtained from your child’s biospecimens may be used in this research or other research, and shared with other organizations. You and your child will not share in any commercial value or profit derived from the use of your child’s biospecimens and/or information obtained from them.

**Will you receive any results from participating in this study?**

You will not receive any individual research results from participating in this study. Your child’s newborn screening results and the results of the advanced testing of 1000 chemicals in dried blood spots will be kept confidential. These results will be analyzed for research purposes to see if they might be used to predict a future risk of developing ASD before the first symptoms appear. If the study is successful, these results will be published in the peer-reviewed scientific literature so they can be used to help other children who may have a risk of ASD.

**Who can you call if you have questions?**

This study has been explained to you and your questions have been answered. If you have other questions or research-related problems, you may reach the Study Coordinator, Dr. Jane C. Naviaux at 619-933-1408, or email at [jnaviaux@ucsd.edu](mailto:jnaviaux@ucsd.edu).

You may call the Human Research Protections Program Office at 858-246-HRPP (858-246-4777) to inquire about your rights as a research subject or to report research-related problems.

**Your Signature and Consent**

You have received a copy of this consent document and a copy of the “Experimental Subject’s Bill of Rights” to keep.

You agree to allow your child to participate.

\_\_\_\_\_  
Parent/Guardian Signature

\_\_\_\_\_  
Date

