Who is conducting the study, why your child been asked to participate, how your child was selected, and what is the approximate number of participants in the study?

Dr. Naviaux and his colleagues are conducting a research study to see if the results of newborn screening (NBS) tests that were collected in California when your child was born can be used to predict the risk of a future diagnosis of Autism Spectrum Disorder (ASD). You and your child have been asked to participate in this study because your child has been diagnosed with ASD, or is a healthy child without any behavioral or medical issues, who is 3-6 years old. Boys and girls are both eligible for this study. Approximately 100-125 children with ASD and 100-125 healthy control children ages 3-6 years will participate in this study.

Why is this study being done?

This study is designed to answer the question: Can newborn screening (NBS) results be used to predict the future risk of autism spectrum disorder (ASD)?

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

No new blood tests are required for this study. Completion of an online questionnaire will be required. This will take less than 30 minutes. Once you have completed the questionnaire and given your written permission, Dr. Naviaux's team will request the results of the newborn screening tests that were done when your child was born. After 200-250 records have been collected, Dr. Naviaux’s team will analyze the results and try to create a way to use the information to predict a future risk of a diagnosis of ASD.

No one has ever tried to use the information from universal newborn screening tests in this way before. We do not know if this will work, but if it does and can be confirmed in follow-up studies, then doctors might one day be able to predict which children are most at risk for ASD and might be able to use early interventions to lower this risk.

If you agree for your child to be in this study, the following is a more detailed description of what will happen:

1. Medical and Family History: The online questionnaire we will ask about 60 questions. Topics will include questions about your pregnancy, labor and delivery, 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. These questions will also help scientists interpret the results of newborn screening tests. We will obtain your written HIPAA release to review medical records for details when needed.
Will DNA results be part of this study?

No. This study will only collect the results of NBS testing that are already on file from when your child was born.

*How much time will each study procedure take, what is your child’s total time commitment, and how long will the study last?*

Your child need not be present to be a participant in this study. To participate in this study we ask that you complete an online questionnaire, which will take less than 1 hour of your time.

*What risks are associated with this study?*

This study does not involve any medical interventions. Participation in his kind of study involves the potential risk of loss of confidentiality. Every effort will be made to keep all information confidential. All identifying material including signed, informed consents will be stored in a locked file cabinet and a password protected computer in Dr. Naviaux’s office at 214 Dickinson St, CTF Rm C115, San Diego, CA 92103-8467.

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.

*What benefits can be reasonably expected?*

There will be no direct benefit to you or your child. However, if newborn screening results are found to predict the risk of a future diagnosis of ASD, there will be a significant benefit to society.

*Can you choose to not to have your child participate or withdraw from the study without penalty or loss of benefits?*

Participation in research is entirely voluntary. You may refuse to allow your child to participate or withdraw your child at any time without penalty or loss of benefits to which you or your child are entitled. If you decide that you no longer wish your child to continue in this study, simply inform any researcher involved in the study, or call Dr. Naviaux directly at (619-993-2904).

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.

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

Your child may be withdrawn from the study by the research team if he or she is found not to qualify for any reason.
Will you be compensated for participating in this study?

You will receive a $40 Amazon eGift certificate as compensation for participating in this study.

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 your child is injured as a direct result of being in this study?

No physical or medical intervention will occur during this study. There is no risk of physical or medical injury to you or your child from this study. There is a small risk of loss of confidentiality or other risks that we cannot predict. You may call The Human Research Protections Program office at (858) 246-4777 for more information about this, to inquire about your child’s rights as a research subject, or to report research-related problems.

What about your confidentiality?

There may be a risk of loss of confidentiality. Research records will be kept confidential to the extent allowed by law. This research project follows strict legal and University of California regulations to maintain confidentiality of all personal information. This means that every reasonable effort is made to secure your information. Study numbers will be assigned and records will use those numbers rather than names whenever possible. Your name and other information that might identify you or your child will be kept strictly confidential and all records that could identify you or your child will be kept in locked cabinets. Research records may be reviewed by the UCSD Institutional Review Board, otherwise only the doctors working on this project and the laboratory staff who record the information will have access to this information.

Who can you call if you have questions?

If you have questions about the study, you may call the study coordinator Rachel Riggs at 619-884-8021. If you have other questions or research-related problems, you may reach Dr. Naviaux at (619-993-2904).

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.
Consent and Bill of Rights

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

What about videos and photographs?

No videos or photographs will be taken as part of this study.

Your Signature and Consent

You agree to allow your child to participate.

__________________________________
Please print your child’s name here

PARENT/GUARDIAN
SIGNATURE

DATE

RELATIONSHIP TO
STUDY PARTICIPANT

Print Name: ________________________________