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

The UCSD Metabolomics Study

Who is conducting the study, why you have been asked to participate, how you were selected, and what is the approximate number of participants in the study?

Dr. Robert K. Naviaux and his colleagues are conducting a research study to find out more about metabolic changes (chemical changes in the body) associated with normal development, aging, disease, and currently used treatments for certain diseases. This study will use a machine called a mass spectrometer to measure metabolites found in blood, urine, saliva, and breath samples that change during normal aging, disease, or treatment for disease. Metabolites are chemicals made by our cells from food and drink. Metabolites are the building blocks that cells use for normal growth and repair. This study will measure up to 1000 chemicals in the blood and urine, and about 100 chemicals in saliva and breath. Some of these chemicals are natural and some are manmade and consumed as part of our food chain, air, and water. This information is experimental and will not be used in any way by your doctors to help in diagnosis or treatment.

You have been asked to participate in this study because you have one of the diseases the investigators are looking at, or you are a healthy person. There will be approximately 600 participants at this site and approximately 1400 participants at all sites.

Why is this study being done?

The purpose of this study is to better understand the role of body chemistry in health, disease, and the effects of currently used remedies and treatments. This is not a treatment study. Your participation in this study is complete upon completing the online and paper survey and submitting a biological sample for analysis.

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

If you agree to be in this study, the following will happen to you:

You will provide a small sample (less than a teaspoon) of one or more of the following first 3 specimens, or a tablespoon-sized sample of breath. You can choose which samples you want to provide by checking the boxes below. If you are receiving a treatment, you may be asked to provide a sample before and after the treatment. However, no treatments will be changed as part of these study. Check the appropriate box(es):

- ☐ Blood
- ☐ Urine
- ☐ Saliva
- ☐ Breath

☐ Dried blood spots collected when you were born

If you are currently nursing a baby, you may volunteer to provide a 1-2 teaspoon sample of breast milk. If this applies to you, please check the box below:

☐ Breast milk

In some cases, you will be asked to provide a sample of one or more of the above sample types on 4 separate occasions. This will occur approximately once a week for 4 weeks. If you agree to providing 4 serial samples over about a 1 month time period, please check the appropriate boxes:

☐ Blood
☐ Urine
☐ Saliva
☐ Breath
☐ Breast milk

In addition to the samples described above, this study will collect the following information from you or your medical records: name, age, sex, height, weight, chief complaint, alleriges, primary diagnosis, secondary diagnoses, current medications, family history, occupational history, and exposure history. In some cases, you will be asked to report the treatments that have worked in the past, and those that did not work, and to list the side effects of treatments you have experienced. This information is collected by completing the Naviaux Lab Basic Data Sheet consisting of about 25 items (BDS25).

In some cases, you will be asked to complete a standardized questionnaire about your health and quality of life. Dr. Naviaux or his associate will describe these to you. Please check the boxes next to the questionnaire(s) below that you agree to complete:

☐ Karnofsky Performance Scale (KPS)
☐ Short Form 36 version 2 (SF36v2)
☐ General Symptom Questionnaire 30 (GSQ30)
☐ Antonovsky's SOC29 resilience questionnaire (ARQ29)
☐ Beck Depression Inventory 21 (BDI21)
☐ ALS Functional Rating Scale Revised 12 (ALSFRS-R12)

You may complete these forms either as hard copies on paper or as a online survey by using a secure link that you will be given upon request.

Your blood, urine, or saliva may also be used in additional research to be conducted by University of California personnel. Some of your samples may be stored for future research. Dr. Naviaux will be responsible for deciding how they will be used. No DNA testing will be done as part of the immediate study. However, future DNA studies may be conducted to better understand the link between metabolism and chronic disease. You will not be provided with any

results or information regarding any DNA testing. These specimens, DNA, and their derivatives, may have significant therapeutic or commercial value. You consent to such uses.

Dr. Naviaux, his associates, or his successors in these studies will keep your DNA specimen and/or the information derived from it indefinitely. If you decide later that you do not want the specimens collected from you to be used for future research, you may tell this to Dr. Naviaux, who will use his/her best efforts to stop any additional studies. However, in some cases, such as if your cells are grown up and are found to be generally useful, it may be impossible to locate and stop such future research once the materials have been widely shared with other researchers.

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

It will take about 5 minutes of your time to collect each sample. If you provide all four samples, it will take about 20 minutes of your time. If you are providing a sample before and after a treatment, it will take about 5 minutes before and 5 minutes after the treatment for each sample.

Your participation in the study is completed upon receipt of the samples and information collected above. There is no commitment to provide additional samples or information in the future. The study will last about 5 years overall.

What risks are associated with this study?

Participation in this study may involve some added risks or discomforts. These include the following:

1. Blood Draws: Taking blood may cause some pain, discomfort, bleeding or bruising/swelling where the needle enters the body, and, in rare cases, dizziness, lightheadedness, fainting, or infection.
2. Weekly Blood Draws for 1 month: Sequential blood draws will increase the risk of pain, bruising, and inflammation. Every effort will be made to use a different vein for collection than was used in the previous week to minimize this risk.
3. Loss of Confidentiality: Participation in this study involves the potential risk of a loss of confidentiality. Every effort will be made to keep your information confidential, as described in the "What about your Confidentialty" section below

Because this is a research study, there may be some unknown risks that are currently unforeseeable. You will be informed of any significant new findings.

What are the alternatives to participating in this study?

The alternative to participation in this study is not to participate. You are under no obligation to participate in this study and can withdraw at any time.

What benefits can be reasonably expected?

There will not be any direct benefit to you from these procedures. The investigators, however, may learn more about metabolic changes that are associated with normal development, aging, disease, and currently used treatments.

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

Participation in research is entirely voluntary. You may refuse to participate or withdraw at any time without penalty or loss of benefits to which you are entitled. If you decide that you no longer wish to continue in this study, you will be requested to tell Dr. Naviaux, or their colleagues. If you also wish your samples and information to be withdrawn, you can send a written request to Dr. Naviaux at 214 Dickinson St. C115, San Diego, CA 92103, and your samples and information will be removed from this study.

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

Can you be withdrawn from the study without your consent?

You may be withdrawn from the study for the following reasons:

1. You or your doctors receive new information that changes your eligibility. An example of this might be a change in your primary diagnosis, ie a change in the name, or revision of the disease that you are being treated for.
2. Dr. Naviaux believes that it is in your best medical interest.

You may also be withdrawn from the study if you do not follow the instructions given you by the study personnel.

Will you be compensated for participating in this study?

There will be no compensation for your participation in this study.

Are there any costs associated with participating in this study?

There may be some cost to you for a blood draw and dry ice for shipping associated with this study. If applicable, this cost should be less than $100. Return FedEx shipping will be provided by the study. If you are able to have your samples collected at Dr. Naviaux's lab in San Diego, there is no cost to you for participating in this study.

What if you are injured as a direct result of being in this study?

This is a sample collection study. No treatment is being tested in this study. If you are injured as a direct result of participation in this research, the University of California will provide any medical care you need to treat those injuries. The University will not provide any other form of compensation to you if you are injured. You may call the Human Research Protections Program Office at (858) 246-4777 for more information about this, to inquire about your rights as a

research subject or to report research-related problems. The University of California will only be responsible for injuries which are directly related to study participation and caused by University of California employees performing research activities within the course and scope of their University of California employment.

What about your confidentiality?

Research records will be kept confidential to the extent allowed by law. All hard copies of medical information including identifying material, signed informed consents, and metabolomic test results will be stored in locked filing cabinets, at Dr. Naviaux's office. Electronic copies of records containing identifying information will be kept on a password-protected desktop computer at Dr. Naviaux's office

All data will be used for scientific analysis only. No information from this study will be made available to anyone other than the P.I., his colleagues, and staff without the your express written permission. Records and test data will be released only upon your request after you sign an approved release of information form. No person-identifiable information will be used for publication or presentation of these studies.

Research records may be reviewed by the UCSD Institutional Review Board.

Federal and State laws generally make it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways: a) Health insurance companies and group health plans may not request your genetic information that we get from this research. b) Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums. c) Employers with 5 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that these laws **do not** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Who can you call if you have questions?

Dr. Naviaux and/or _____ has explained this study to you and answered your questions. If you have other questions or research-related problems, you may reach Dr. Naviaux at 619-543-2904.

You may call the Human Research Protections Program Office at (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 participate.

_____ _____

Subject's signature Date

_____

Print your name