Participant Information and Consent
Viome Study Protocol No. 001.v3.0, Collection and Analyses of Physiological, Physical, and Molecular Data from a Diverse Population

Please read this consent form. In order for Viome to analyze your samples or data, you will need to acknowledge that you have read this document.

Summary

If you are a paying customer, you will receive your test results and personalized diet and supplements recommendations, which are based on our analysis of samples and other information you provide to us, provided that you give Viome the requisite materials/information. Non-paying study participants may be rewarded either by receiving free Viome service or a monetary reward. Study recruitment letter will provide detailed information. Viome reserves the right to not provide results and recommendations to non-paying study participants.

What will happen if I agree to participate in the study?

You will be asked to provide certain samples and other information about yourself. You may choose not to provide all the samples and/or answer all questions. However, not doing so may not allow Viome to make personalized recommendations.

- Create an account on the Viome app and/or the Viome website.
- Answer the questions in the app and/or the Viome website. Some questions relate to mental health, anthropometric measurements, skin conditions, etc.
- Track your diet with an app.
- Collect some or all of the following samples: blood, stool, saliva, cheek swab, skin swab, and/or urine. We will provide you with sample collection kits. You will submit the samples to the Viome labs for analysis. You may collect all samples at home. Follow good hygiene practices when collecting samples. For example, wash your hands with soap and water before and after sample collection. Wipe your finger with an alcohol swab before doing the blood prick. Use the sterile lancets as single use only. Do not touch the urine or stool samples with your bare hands.
- Allow Viome to track the location of your smart device for gathering publicly available environmental data for your location (you will be asked for this permission within the app).

In addition to the above requirements, if you are a non-paying participant, you may be asked to perform the following tasks (detailed information will be provided in the recruitment letter):

- Consume specific meals which may be allergenic, not abide by your dietary restrictions, or cause discomfort. You may be asked to consume these meals at designated times. The provided foods may not be wholly appetizing.
- Measure your blood glucose with a glucose monitor that is cleared by the FDA and will be provided to you by Viome. This includes continuous glucose monitoring and HbA1c testing.
- Perform an online cognitive test. These tests assess your reaction speed, short term memory, logic, reasoning, etc. They will be used to assess whether specific dietary and lifestyle changes you implement will result in improved cognition.
- Provide a blood sample from your arm.
- You may need to be physically present at one of Viome's offices in order to interact with the research staff, receive study materials, consent, and provide samples.

- Receive a wearable device. You may choose to wear the device continually. This device may monitor your heart rate, activity, respiratory rate, temperature, oxygen saturation, and/or sleep.
- Choose to wear your own activity tracker and provide the data from the tracker to Viome.
- Allow Viome staff to take additional physiological measurements.

Depending upon what samples you provide, Viome will do the following types of analyses:

- Gut, mouth, or skin microbe analysis to identify and quantify all bacteria, viruses, parasites, etc. living in your gut or mouth, or on your skin.
- Microbial gene expression analysis to measure the biochemical activities of the microbes.
- Gut metabolite analysis to measure indicators of microbe activity.
- Personal genetic analysis to understand possible connections between your genes and your health, wellness, and lifestyle. We will not sequence your genome or exome, or look for rare single gene inherited diseases.
- Personal gene expression analysis to understand possible connections between the activities of your genes and your overall well-being.
- Personal metabolite analysis to understand how your body is working at a molecular level.
- Food sensitivity analysis to quantify antibody responses to specific foods.

Your data will be saved on the Viome secure cloud servers. Viome will analyze your data and will send you a report if you are a paying customer. You may choose to follow Viome recommendations. If the report has information that may be important to your medical health, you may choose to seek medical advice from licensed professionals. All Viome results will need to be confirmed in a reference laboratory before your doctor can use them.

Your de-identified samples and data can be used for future research studies without your additional informed consent. If your de-identified samples or data are sold for commercial profit, this profit will not be shared with you.

What are the benefits of being in the study?

If you are a paying customer, you will receive results of the Viome tests and personalized diet and supplements recommendations. This guidance may help you reach your wellness goals. However, it cannot be guaranteed that these recommendations will benefit your wellness. The analysis provided by Viome is not intended, and should not be used, for treating or curing any medical condition. Information provided by Viome must not be used as a substitute for any medical treatment.

Viome's goal is to make scientific discoveries about how complex biological systems are associated with healthy living in order to provide people with diet and lifestyle advice. If Viome makes any such discoveries or sells any products or services as a result of this study, you will not receive any payment. You may, however, benefit in the future as scientific knowledge increases.

What are the possible risks of being in this study?

The study has potential risks as shown below:

- You may feel minor pain from the lancet device used to collect blood from the tip of your finger. This will likely be minor and should stop with pressure. The puncture site could

become infected, although this is rare.

- There is also a chance that you may faint or feel like fainting.
- Viome may recommend foods to which you are allergic or sensitive. If you have a known allergy or sensitivity do not follow that recommendation. Also, please inform Viome which foods you have issues with when you fill out the questionnaire on the Viome website or app.
- Your condition may not get better or may get worse during this study.
- You or your family members may feel uncomfortable with some of the survey questions. You may choose not to answer any such questions. However, this may make it impossible for Viome to provide you with personalized recommendations.
- A safety breach could result in release of your data and/or personal information. This could happen, for example, if the lab or data storage systems are broken into. This may also happen if study staff fails to follow the study protocol. If your private data or information is wrongly made public, it may be upsetting to you and/or your family. You will be told of any known safety breach that results in your data and/or personal information wrongly released to the public.
- Your personal health data will be labeled with a code and not with your name or other personal information. However, human genetic data are unique and might be used to identify you. It is also possible that your DNA data could be used to identify your family, since you and your family members share DNA.
- Some DNA data can help to predict future health problems. This information might be of interest to health providers, life insurance companies, and others. A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers (those with over 15 employees) to discriminate against you based on your genetic information. GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. By participating in this study, you are not giving up any of your rights.
- Viome results and/or recommendations may make you want to seek medical attention. You will be responsible for the costs of this follow-up testing and possible treatment. Any follow up care with your primary care provider could potentially affect your insurance.
- You may find out information about yourself that will cause you to worry or become anxious.
- There may be unknown risks to participation that we cannot predict at present.
- Non-paying participants who are asked to donate venous blood may also experience minor pain and bleeding from the puncture.

All of the procedures used by Viome in this study are low risk. Viome will not provide any payment or treatment if you have an injury while you are part of this study. By participating in this study you are not giving up any of your rights.

How will Viome protect and secure my private information?

- Viome takes privacy very seriously. We keep all personal data private. Only a small group of study staff can access information that can be used to identify you. These are people who need that information to complete the testing, analysis, and reporting.

- Your personal health information will be labeled with a code and not your name. Only a small group of study staff will have access to the protected database.
- Viome will not include any information in any reports they publish that would make it possible to identify you.
- All Viome employees, consultants, and others who might have access to your private information will sign Confidentiality Agreements that mandate them to keep that information private. However, the study sponsor (Viome), regulatory agencies and the institutional review board will have access to all documents for auditing purposes.
- Your private information will not be shared with any insurance providers.
- Your specimens will be analyzed, and remnants will be securely stored until the study is completed.
- During the sign-up process, you will acknowledge that you have read the consent form and agree to participate in the study, provide personal and health information, and make your payment on the Viome website. If you are a non-paying participant, a paper copy of the consent form may be provided with the sample kit to you, or you may print a PDF of the consent form. In that case, you must return or scan and email the signed paper consent form along with the sample in order for the sample to be analyzed. Scanned forms will be stored in the study's cloud-based data storage system. Access to consent documents is restricted to only those study staff who need to see the consent forms as part of their study responsibilities.
- Access to your samples and information is restricted to the study staff who have taken the "NIH Protecting Human Research Participants Course" and signed a Confidentiality Agreement.

Will it cost me anything to participate in the study?

There is a fee to participate in the study. Up to date fee information for all Viome services is described on the Viome website:

www.viome.com

The fee will depend on the type of Viome product/service that you choose, and how long you wish to take part in the study. The fees shown on the Viome website for the product/service that you choose will always include *all* Viome services, such as Viome kits, Viome laboratory analyses (tests), shipping and handling, data interpretation, the use of Viome app and website resources, etc. There will be no additional charges or fees for participating in the research study.

If you do not wish to continue as a participant in this study, you can leave the study at any time and there will be no additional expenses.

Will I be paid to take part in the study?

As a paying Viome customer, you will not be paid by Viome. However, there may be opportunities to become a non-paying study participant, in which case you may receive a reward for your participation. The reward will either be a free Viome service or a monetary reward. The recruitment letter clearly specifies the reward type and quantity. Viome reserves the right to not provide results and/or recommendations to any participant.

How long will my samples and data be kept?

Your samples will be analyzed, and any left-over will be securely stored until the study is completed. Study data will be kept indefinitely by Viome.

Can I refuse to participate, or withdraw from the study?

- The decision to participate in this study is voluntary. You may refuse to take part in the study *at any time*.
- You have the right not to answer any question. However, Viome may not be able to provide you with your results and recommendations.
- If you are a Viome employee, your job will not be affected in any way if you choose to take part in the study, or if you choose not to take part in the study.
- You may withdraw from the study at any point during the process. When you withdraw from the study, no new health information will be gathered from you after that date. However, once we analyze your samples and place the information in the database, you will not be able to withdraw the information. Viome may also not provide you with the results and/or recommendations if you withdraw from the study.
- The study investigators retain the right to end your participation in the study at any time.

What are my alternatives to participating in the study?

This is not a treatment study. Your alternative is to not participate in the study.

Can I ask questions about the study, and how do I report concerns?

You have the right to ask questions about this research study and to have those questions answered before, during or after the research. If you have any further questions about the study, or have a concern about safety or experience harm or injury from participating in the study feel free to contact info@viome.com.

You may also contact the Principal Investigator, Momchilo Vuyisich PhD and/or the Sub-Investigator and Medical Monitor, Helen Messier PhD, MD at consent@viome.com.

Viome is a private company. The Principal Investigator of this study is also the Chief Scientific Officer of the company. There may be a conflict of interest between these roles; however, the Principal Investigator and the Physician Sub-Investigator are obligated to hold the interests of your welfare and the research above those of the company for purposes of the research study.

Participant Information and Informed Consent Signature Page
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Consent

- Your signature below indicates that you have decided to participate as a research subject for this study, that you have read the information provided in the Consent to Participate form, and have had the opportunity to discuss with the Investigator, Sub-Investigator and/or Study Staff any questions or need for clarification regarding the study.

Consent form version: _____

Participant Name: _____

Participant Signature: _____ Date: _____

Received at Viome by: _____ Date: _____