INFORMED CONSENT FORM

Sponsor / Study Title:	**FitBiomics, Inc. / "Project V – A randomized controlled prospective study of the next-generation probiotic, Veillonella atypica FB0054, vs placebo in healthy adults"**
Protocol Number:	**FB004**
Principal Investigator:	**Jonathan Scheiman**
Telephone:	**(855) 843-3265** **(866) 327-7282 (24 Hours)**
Address:	**Fitbiomics, Inc.** **180 Varick St.** **6th Floor** **New York, NY 10014**

KEY INFORMATION

You are invited to take part in a research study. This is a research study to test a new investigational product. An investigational product is one that is not approved by the United States Food and Drug Administration (FDA). This research study is investigating Veillonella (*Veillonella atypica* FB0054) as a possible supplement for reducing fatigue (tiredness) and improving endurance. FitBiomics, Inc. is sponsoring this research study.

Veillonella is a novel probiotic that can metabolize lactic acid into propionate, which is an energy source for the body. Early animal data and a pilot human clinical study have shown that Veillonella is safe and can improve endurance and decrease fatigue. FitBiomics is sponsoring this study to confirm these effects in a broader population. FitBiomics is the first company to develop this type of bacteria as a probiotic, and this will be the largest study testing the effects of this probiotic.

This study will take place over 8 weeks and include taking a daily probiotic capsule containing one of two doses of Veillonella or a placebo (inactive substance) containing microcrystalline cellulose. Throughout the 2 week baseline, 4 week supplementation period, and 2 week washout, participants will not make any major changes to their lifestyle and fill out daily and weekly surveys assessing changes in sleep, fatigue, and other habits. Surveys will be delivered using the Chloe app, made by PeopleScience. At the end of the study, participants will be able to see for themselves how their sleep, fatigue, and other habits changed over time – during and after supplementation - compared to their personal baseline.

We will collect the survey data alongside any fitness tracker information participants are willing to share with us. All personal identifying information will be removed before analysis. All data collected as part of this study will be used by FitBiomics for research purposes only and never given away or sold to anyone. The results may be used to market Veillonella, publish papers, file patents, and develop new products.

Study participants can earn in-app rewards through Chloe by completing as many surveys as possible. All participants who complete the study will receive a 50% off Nella coupon. Participants who received placebo capsules and complete the study will also receive a coupon code for a 1 month supply of Veillonella when the product launches.

Participants may join this study if they are generally healthy adults who are interested in potentially decreasing feelings of fatigue and improving endurance in their daily life by taking a daily probiotic. Taking this product will not interfere with use of other probiotics, access to medications, treatments, or other dietary supplements. By joining this study, participants will have early access to Veillonella prior to product launch, and by using a fitness tracker and filling out the surveys, they will be able to see for themselves whether Veillonella provides them with any benefits related to sleep, fatigue, energy, and endurance.

Participants should not join the study if they are pregnant or planning to become pregnant in the near future. Furthermore, participants should not join the study if they have a chronic condition or disease that results in a disrupted gut barrier, an immunocompromised state, or other medical condition that would prevent them from taking a daily probiotic. While 80% of participants in the study will receive Veillonella, 20% will receive placebo. At the end of the study, participants will be notified whether they received Veillonella or placebo, but if taking a placebo is a concern, participants should not join the study.

An investigator on this study has an ownership interest in Fitbiomics, the company sponsoring this research study, invented the study drug being investigated in this research study, Veillonella atypica FB0054, and owns the patent to it, and serves on the Board of Directors. As a result, the investigator may benefit financially from a successful study. Additional steps have been taken to manage the potential conflict of interest that this financial arrangement may create. Please speak with your study doctor if you have questions about this.

BACKGROUND AND PURPOSE

You are being asked to participate in this research study because you are a healthy adult and have expressed interest in supplementation with Veillonella (*Veillonella atypica* FB0054) in order to decrease fatigue or improve endurance.

In previous research, we have shown that Veillonella may improve endurance compared to placebo. In mouse studies, those mice who supplemented with *V. atypica* ran 13% longer in a run-to-exhaustion test than those mice who were given placebo. Furthermore, in a pilot randomized controlled crossover pilot study, we showed that Veillonella prevented 78.7% of the performance decline observed in the placebo group in a run-to-exhaustion model. We have also conducted experiments that have resulted in this product being deemed Generally Regarded As Safe (GRAS).

Therefore, we believe the Veillonella is safe and likely to provide significant benefits in terms of improved endurance, increased energy, and decreased fatigue. This research study is designed to test that hypothesis.

The purpose of this research study is to:

- Test the safety and effectiveness of the study product, Veillonella (*Veillonella atypica* FB0054), a novel probiotic strain.
- Identify the types of benefits observed in a broad population

While Veillonella has been used in humans previously, this will be the largest study assessing its safety and efficacy. About 1,000 participants will participate in this study.

WHAT WILL HAPPEN DURING THE STUDY?

Your participation in this study will last approximately 8 weeks and will include zero in person study visits to the study site. However, there will be short daily and longer weekly surveys throughout the 8 week study using the Chloe App. If participants are willing to share fitness tracker data, these data will also be collected.

<u>Screening</u>:

Before any study-related tests and procedures are performed, you will be asked to read and sign this consent document. An initial screening survey will also be used to determine if you qualify to take part in this study.

If you qualify to take part in this study and go on to receive the study treatment, then the following will happen:

- You will be invited to download the Chloe app, which will include study instructions, survey assessments, and other study details
- You will provide your mailing address, so we can ship you the study product
- You will take an initial baseline survey followed by providing daily and weekly survey data for 2 weeks.
- After 2 weeks of baseline, you will begin supplementation, while continuing to provide answers to the surveys. There will be 4 weeks of supplementation.
- After supplementation, there will be a 2 week washout period with no supplementation, while continuing to provide answers to the surveys.

Study Treatment:
The study product here includes one of two doses of Veillonella or placebo. Veillonella contains *Veillonella atypica* FB0054 as the active ingredient with microcrystalline cellulose and hypromellose as excipients. Placebo capsules contain microcrystalline cellose and Hypromellose. Both Veillonella and placebo are encapsulated in acid-resistant capsules, which participants will take orally at home on a daily basis.

You will be randomly assigned by chance (like the flip of a coin) to receive either one of two doses of Veillonella or placebo (inactive substance). You will have a 80% (4 in 5) chance of receiving Veillonella and a 20% (1 in 5) chance of receiving placebo. This is a single-blind study, which means you will not know whether you were assigned to placebo or Veillonella but the investigator and study staff will. In case of an emergency, however, the study staff can get this information to you or your physician.

There will be no in person study visits or procedures. However there will be the following assessments delivered to your mobile device via the Chloe app.

- Baseline health, lifestyle, and habit survey
- Daily surveys assessing sleep, energy, and bowel movements
- Weekly surveys assessing general health, fatigue, energy, and recovery
- Multi-dimensional fatigue inventory survey taken pre and post supplementation
- General self-efficacy survey taken pre and post supplementation
- An end of study survey to assess final thoughts and experiences.

After Study Treatment:
Because this is a research study, the study product will be given to you only during this study and not after the study is over. There is no follow-up from the investigator after the study ends.

EXPECTATIONS
If you participate in this study, you will be expected to:

- Complete all surveys
- If willing, connect your fitness tracker to the app and share your data

RISKS, SIDE EFFECTS, AND/OR DISCOMFORTS

For Veillonella:
Very common (greater than or equal to 1/10)

- Mild gastrointestinal upset including temporary increases in gas, bloating, cramping, and nausea
- Nervousness and increased feelings of anxiety

For Placebo:
None known

Allergic Reaction Risks

As with taking any product, there is a risk of allergic reaction. If you have a very serious allergic reaction, you may be at risk of death. Some symptoms of allergic reactions are:

- Rash
- Wheezing and difficulty breathing
- Dizziness and fainting
- Swelling around the mouth, throat or eyes
- A fast pulse
- Sweating

Please seek treatment immediately and tell the study doctor and study staff if you have any of these symptoms.

RISKS OF STUDY PROCEDURES

- Questionnaires: The surveys used in this study may be upsetting. Contact study staff if there are questions you are not comfortable answering.
- Mobile App: As part of this research, you may be required to use one or more of the following: a phone or web app/ site, an electronic study diary (eDiary), or a device that tracks information about you. While using these, information about you may be collected and shared with the researchers or people outside of the study. This data might include personal health information, location, call logs, text message history, web browsing history, or social media use. A complete description of the data collection and sharing for an app, eDiary, or device can commonly be found in the Terms of Use, End User License Agreement, or Privacy Policy associated with the device. If you would like to read these documents, request a copy or instructions about how to access this information from the investigator.

  While the Terms of Use, End User License Agreement, or Privacy Policy may include statements limiting your rights if you are harmed as a result of your use of the app, eDiary, or device in this study, you do not release the investigator, sponsor, study site, or agents for responsibilities from mistakes. You also do not waive any of your rights as a research participant.

UNFORESEEN RISKS

There may be other risks that are unknown. Additionally, there may be unknown risks to a pregnancy, embryo, or fetus if you or your female partner become pregnant.

BIRTH CONTROL RESTRICTIONS

Taking the study product may involve risks to a pregnant woman, an embryo, fetus (unborn baby) or nursing infant. Therefore, if you are pregnant, planning to become pregnant, planning to father a child, or are breastfeeding a child, you cannot participate in this study.

ALTERNATIVES TO PARTICIPATION
This research study is for research purposes only. The only alternative is to not participate in this study.

NEW FINDINGS
Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be provided to you.

BENEFITS
This study is for research purposes only. There may be no direct benefit to you from your participation in the study. Information learned from the study may help you and other people in the future.

COMPENSATION FOR PARTICIPATION
For every completed survey, you will receive Chloe points and become eligible for awards like Amazon gift cards through the Chloe application. If you complete the entire study, you will receive 1220 Chloe points. Furthermore, those that complete at least half the surveys during each of the baseline, supplementation, and washout periods will be eligible for a 50% off coupon to purchase Nella probiotics. Finally, those that received placebo and completed at least half the surveys during each of the baseline, supplementation, and washout periods will be compensated with a coupon for 1 free month of Veillonella upon product launch.

You will not receive any monetary compensation for your participation in this study. If you have any questions regarding your compensation for participation, please contact the study staff.

CONFIDENTIALITY
Records of your participation in this study will be held confidential except when sharing the information is required by law or as described in this informed consent. The Investigator, the sponsor or persons working on behalf of the sponsor, and under certain circumstances, the United States Food and Drug Administration (FDA) and the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify you by name. This means that absolute confidentiality cannot be guaranteed. This does not limit the duty of the researchers and others to protect your privacy. Your study records including confidential information about you collected during the study will be kept at a secure location. If the results of this study are published or presented at meetings, you will not be identified.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

By signing this information and consent form, you consent to the collection, access, use and disclosure of your information as described above.

COMPENSATION FOR INJURY

If you become ill or are injured while you are in the study, get the medical care that you need right away. You should inform the healthcare professional treating you that you are participating in this study. If you tell the study staff that you think you have been injured or ill then they will help you get the care you need.

If you are injured or ill as a result of taking the study products or from procedures done for the purpose of this study, the sponsor will pay for those medical expenses necessary to treat your injury that are not covered by your medical insurance or any other third-party coverage. By signing this document, you will not lose any of your legal rights or release anyone involved in the research from responsibility for mistakes.

To pay medical expenses, the sponsor will need to know some information about you like your name, date of birth, and Medicare Beneficiary Identifier (MBI). This is because the sponsor has to check to see if you receive Medicare and if you do, report the payment it makes to Medicare.

COSTS

There will be no charge to you for your participation in this study. The study product, study-related procedures, and study visits will be provided at no charge to you or your insurance company.

FUTURE RESEARCH STUDIES

Identifiers might be removed from your identifiable private information or identifiable biospecimens collected during this study and **could then be used for future research studies or distributed to another investigator for future research studies** without additional informed consent.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research participant;
- Eligibility to participate in the study;
- The Investigator's or study site's decision to withdraw you from participation;
- Results of tests and/or procedures;

Please contact the Investigator at the telephone number listed on the first page of this consent document.

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, contact:

- By **mail**:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00071307.

CONSENT FOR OPTIONAL SUB-STUDY

You are also being asked to consent to providing fitness tracker information as part of this study.

Risks/Benefits

There are no additional risks/benefits to participate in this aspect of the study. You will not be provided with a fitness tracker and must use one that you already own. By linking your fitness tracker to the Chloe application, some aspects of the surveys will be automated, and when you are provided your results at the end of the study, some of the data may be more precise.

Confidentiality

Records of your participation in this study will be held confidential except when sharing the information is required by law or as described in this informed consent. The Investigator, the sponsor or persons working on behalf of the sponsor, and under certain circumstances, the United States Food and Drug Administration (FDA) and the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify you by name. This means that absolute confidentiality cannot be guaranteed. This does not limit the duty of the researchers and others to protect your privacy. Your study records including confidential information about you collected during the study will be kept at a secure location. If the results of this study are published or presented at meetings, you will not be identified.

Alternatives

This research study is for research purposes only. The only alternative is to not participate in this study.

Compensation

There is no additional compensation for participation in this aspect of the study.

Costs

There are no costs associated with participation in this aspect of the study.

You may decide not to participate in the optional sub-study. If you decide not to participate in the sub-study, your decision will have no impact on your ability to participate in the main study and will have no impact on any other benefits to which you would otherwise be entitled.

Please indicate your preference below:

❒**YES** _____ **(initials)** I agree to participate in the sub-study described above.

❒**NO** _____ **(initials)** I do not agree to participate in the sub-study described above.

VOLUNTARY PARTICIPATION / WITHDRAWAL

Your decision to participate in this study is voluntary. You may choose to not participate or you may withdraw from the study for any reason without penalty or loss of benefits to which you are otherwise entitled and without any effect on your future medical care. However, please note that the FDA requires that any information collected up to the point of your withdrawal cannot be removed from the study.

The Investigator or the sponsor can stop your participation at any time without your consent for the following reasons:

- If it appears to be medically harmful to you;
- If you fail to follow directions for participating in the study;
- If it is discovered that you do not meet the study requirements;
- If the study is canceled; or
- For administrative reasons.

Informed Consent Signature

By signing the electronic Informed Consent Form below, you are confirming the following:

(i) I confirm that I have read and understood the information for the above study and have had the opportunity to ask questions.

(ii) I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.

(iii) I understand that the Sponsor of the clinical study, others working on the Sponsor's behalf, the ethics committee and the regulatory authorities will not need my permission to look at my information collected in the research platform for purposes of conducting this current study and for any further research analysis.

By signing below, I agree my handwritten signature on this electronic document is the legal equivalent of my handwritten signature on a paper document. I will receive a copy of this signed consent document.

First Name _____

Last Name _____

Signature _____

Today's Date _____