The Ohio State University Consent to Participate in Research

Study Title:	**Bioavailability and pharmacodynamics of eicosapentaenoic acid and docosahexaenoic acid in soymilk and commercial supplements**
Principal Investigator:	**Dr. Yael Vodovotz**
Sponsor:	NA

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

Key Information About This Study

The following is a short summary to help you decide whether or not to be a part of this study. More detailed information is listed later in this form.

Omega-3 fatty acids are part of fats or oils that may support health. The purpose of this research study is to gain information on how omega-3 fatty acids are taken up, changed, and moved throughout the body. We will be measuring blood levels of components of fats and oils including omega-3 fatty acids and their breakdown products over time.

Omega-3 fatty acids can be found in fish and algae. These oils can be removed from fish or algae to make fish oil or algae oil. For this study, we will be using algae oil as our source of omega-3 fatty acids. Two different products will be tested in this study, a commercial algae oil pill and a flavored soymilk drink containing algae oil. You will receive one of the two products.

The study will last approximately 6-7 weeks.

1. Why is this study being done?

This study is being done to look at differences in how our bodies take in and move omega-3 fatty acids based on how they are consumed, in a drink or as a pill.

2. How many people will take part in this study?

24 people will take part in this study

3. What will happen if I take part in this study?

During the study, you will drink one 12-oz bottle of flavored soymilk or take 2 pills containing algae oil each day.

Throughout the study, we will ask you to record the time that you consume the drink or take the pills each day as well as any side effects such as bad breath or digestive issues.

During the study you will be asked to follow a low marine omega-3 diet which is limited in fish, shellfish, and EPA or DHA fortified foods. If you do accidentally eat one of the restricted foods, we just ask that you make a record.

During the first week, we will ask you to fill out a food frequency questionnaire which will give us information on your overall diet. This questionnaire will be administered online.

One or three times throughout the study, you will be asked to fill out a survey about your opinion of the drink including liking and levels of different flavors and smells, texture, and how the drink looks.

There will be **4 clinic visits** during the study, at two-week intervals. The visits will take place at the OSU Clinical Research Center. At each visit, you will give about 25 mL of blood, or about 2 tablespoons. At each visit, we will also take your height, weight, blood pressure, heart rate, and temperature.

4. How long will I be in the study?

The study will last 6 to 7 weeks.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

6. What risks, side effects or discomforts can I expect from being in the study?

The risks of participating in this study will be minimal if you meet the inclusion criteria (are not allergic to the soymilk or pill ingredients and do not take certain medications).

Possible side effects of omega-3 supplements can include bad breath, bad-smelling sweat, headache, and gastrointestinal symptoms such as heartburn, nausea, and diarrhea.

Having blood drawn may produce discomfort or minor bleeding and the possibility of bruising at the site of the needle puncture. There is also a slight risk of infection at the site of the needle puncture. Although rare, some people have experienced nausea, light headedness, and fainting in association with a blood draw. Trained medical personnel will perform the blood collection procedures and will make every effort to minimize any discomfort.

7. What benefits can I expect from being in the study?

You likely will not benefit directly from participating in the study, as the benefits of the algae oil products are unknown and modest at best over such a short period of time. Rather, the greatest benefits likely will be to the world of scientific research and the greater public.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office records. Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information.

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

You may also be asked to sign a separate Health Insurance Portability and Accountability Act (HIPAA) research authorization form if the study involves the use of your protected health information.

10. Will my de-identified information and bio-specimens be used or shared for future research?

Yes, it/they may be used or shared with other researchers without your additional informed consent. You do you have the option to opt out of this additional use. Please check a box below.

☐ Yes, you may use my de-identified information and/or biospecimens for future research.

☐ No, do not use my de-identified information and/or biospecimens for future research.

11. What are the costs of taking part in this study?

There are no costs related to participation in this study.

12. Will I be paid for taking part in this study?

You will be compensated for each clinic visit. You will receive $20 at the first 3 visits and $40 at the last visit.

By law, payments to participants are considered taxable income.

13. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

14. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of research participants.

15. Who can answer my questions about the study?

For questions, concerns, or complaints about the study you may contact the principal investigator, Dr. Yael Vodovotz at 614-247-7696 or Vodovotz.1@osu.edu. You may also contact the study coordinator, Abigail Sommer at 317-508-7748 or sommer.155@osu.edu.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact **Yael Vodovotz** at 614-247-7696 or Vodovotz.1@osu.edu.

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form**.**

Printed name of participant	**Signature of participant** **AM/PM** **Date and time**
Printed name of person authorized to consent for participant (when applicable)	**Signature of person authorized to consent for participant (when applicable)** **AM/PM**
Relationship to the participant	**Date and time**

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent** **AM/PM** **Date and time**

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness	**Signature of witness** **AM/PM** **Date and time**
Printed name of witness	**Signature of witness** **AM/PM** **Date and time**