Cover Page

Document: Informed Consent Form

Official Study Title: Achieving Nutritional Adequacy Of Vitamin E With An Egg/Plant-Based Food Pairing

ClinicalTrials.gov ID: NCT04287816

Document Date:

- Informed Consent Form Study-1: 12/07/2020
- Informed Consent Form Study-2: 12/07/2020
- Informed Consent Form Study-3: 07/28/2022

The Ohio State University Consent to Participate in Research

Study Title:	Achieving Nutritional Adequacy Of Vitamins E and K With An Egg/Plant-Based Food Pairing – Study 1
Principal Investigator:	Richard S. Bruno
Sponsor:	Egg Nutrition Center / American Egg Board

- **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.

The purpose of this research is to understand how the absorption of vitamin E and vitamin K found in vegetables like spinach can be improved when eaten along with other foods like eggs that contain fat. If you choose to participate in this study, your involvement would span approximately 12 weeks. During this period, there will be 6 nutrient absorption trials. Each trial would last 72 hours and a trained individual would be collecting blood samples periodically from your arm (11 in total). However, you will be free to come and go from our study center during each trial. The primary risk in this study relates to the small initial pain, bruising, or lightheadedness you may experience during blood collection. There are no costs to you to participate in this research and benefits to you include receiving some of your blood testing results like glucose along with your blood pressure and body mass measurements.

1. Why is this study being done?

Vitamin E and vitamin K are two important nutrients for human health. However, the majority of Americans eat diets that are lacking in these nutrients. In addition, when we eat vegetables containing these high levels of nutrients, their absorption into the body will be poor if sufficient amounts of fat are not eaten along with the vegetables. The combination of a poor diet that is low in vegetables and not eating vegetables with sufficient fat therefore increases the likelihood of having low levels of vitamin E and vitamin K in the body where they are needed to promote health. Studies in humans clearly show that dietary fat is important for the absorption of vitamin E and vitamin K. However, limited information is available to indicate how much fat is optimal and whether fat specifically from eggs can help promote absorption of these nutrients. By successfully completing this study, we expect to demonstrate the benefits of eggs, by way of their fats found in the yolk, to improve the absorption of vitamin E and vitamin K that are naturally present in spinach.

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

Our goal is to recruit healthy 10 men and women between the ages of 18-65 years. To meet this goal, we plan to screen up to 20 individuals.

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

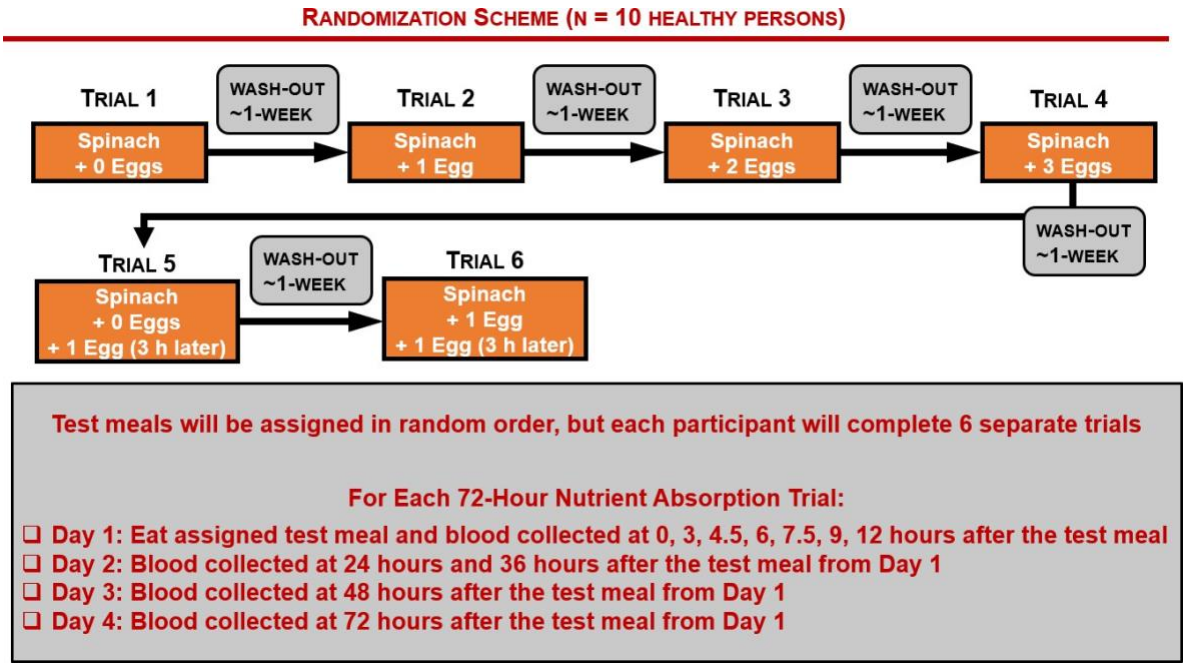
Screening
Before participating in this study, you will need to visit our study center located in 219 Campbell Hall (1787 Neil Ave) on the Ohio State University campus for an initial blood screening to make sure you have fasting blood chemistries (glucose, triglyceride, cholesterol, hematocrit, and hemoglobin) that are consistent with our study criteria. During this time, an experienced technician will measure your blood pressure and collect a small blood sample (2 teaspoons) from your arm. Within a week, we will have determined your blood results, which we will provide to you. If your blood results are consistent with our study criteria, you will be eligible to continue with the study procedures. If not, you will not be able to participate in our study.

Study Overview
For this study, everyone will complete 6 separate nutrient absorption trials that are separated by at least 1 week. For 3 days prior to each nutrient absorption trial and the first day of each trial, we will be providing all of your foods and beverages. You will eat the same foods for each of the 6 nutrient absorption trials. During each trial, which will be completed over the course of 72 hours, you will receive a test meal containing spinach alone or in combination with eggs or other foods. Each test meal will be assigned by chance, but you will complete all test meals throughout the course of your participation in this study. If you are interested in

learning about the final results of the study, we would be happy to email you a copy of the published study findings.
If you participate in this study, you will be scheduled at your convenience to visit our study center a total of 12 times after the initial screening meeting for the first trial, which includes picking up meals, having your height and weight measured, eating a test meal, and then allowing us to collect blood immediately before eating the test meal and then again at 3, 4.5, 6, 7.5, 9, 12, 24, 36, 48, and 72 hours after eating each test meal. You do not need to remain at our study center during this entire time and are free to leave between each study visit. For the 3 days prior and the first day of the study, we ask that you avoid consuming foods/drinks other than the ones we give to you. The amount of food given will be tailored to your caloric needs so that you maintain the same weight throughout the study. The meals will be cooked and ready to eat; a microwave may be used to reheat food if desired.

Additionally, the menus will be customized to your personal calorie level needed for weight maintenance. It is recommended (but not required) that you eat all that is provided to you so you maintain the same weight throughout the study. It is important to our study that you consume only the foods that we provide and not substitute any other foods without first discussing with the study coordinator. We will also give you a form to record any accidental intake of additional foods/drinks.

We also ask that you do not exercise for more than 7 hours per week throughout the entire study. For each morning visit to our study center, you will need to be fasted for 10-12 hours (no food or drink except for water). Please refer to the picture below for a visual overview of the study.



This study consists of 6 trials that are each 72 hours in duration. For each trial, you will visit the study center once approximately 3 days prior to starting the trial to pick up your foods and beverages. You will then visit the study center 11 times over 72 hours so we can collect a blood sample: 7 times on the first day, 2 times on the second day, 1 time on the third day, and 1 time on the fourth day. During each of these 11 blood draws, we will be collecting approximately 1 tablespoon of blood for each of the first 7 blood draws. For the remaining 4 blood draws, we will be collecting 0.5 tablespoons of blood each time. This will be approximately 0.6 cups of blood in total during each nutrient absorption trial. On the first day, you will also eat a test meal containing spinach alone (Trial 1), spinach with 1, 2, or 3 whole hardboiled eggs (Trials 2-4), spinach alone followed 1 egg 3 hours later (Trial 5), or spinach with 1 egg plus an additional egg 3 hours later (Trial 6).

For each morning visit on day 1, day 2, day 3, and day 4, we ask that you fast overnight for 10 hours, which means eating no foods or beverages other than water. After day 4, you can resume your normal daily activities. After about a week, we would like you to return to the study center to complete Trial 2. After this trial and another period of a week, you will return for Trial 3. After Trial 3 and another rest period of a week, you will return for Trial 4. After Trial 4 and another period of one week, you will return for Trial 5, and then after another rest period of about a week, you will return to the study center for Trial 6.

The below describes the procedures that will occur during each Trial.

Study Visit 1. This visit occurs approximately 3 days prior to your scheduled 72 hour nutrient absorption trial. Please return to our study center to pick up an insulated cooler containing your foods and beverages for the entire 3 days prior to starting your scheduled trial. This visit will be brief, no blood samples will be collected, and will last less than 15 minutes.

Study Visit 2 (Day 1 of Trial). We ask that you do not consume any food or drink except water for 10-12 hours prior to your study visit. Prior to providing you the test meal, we will measure your height, weight, waist circumference and blood pressure. We will then collect a 16 mL blood sample (1 tablespoon) for your 0 hour blood collection. You will then be asked to eat the test meal within 10 minutes. From that point, we ask that you remain in close proximity to our study center so that you may return for blood collection at 3, 4.5, 6, 9, 7.5 and 12 hours after eating the test meal. For each of these 6 blood draws, we will collect a 16 mL blood sample (1 tablespoon). On this day, we will also provide you lunch and dinner because it is important for our study to control your food intake. Each of the 7 blood collections during this day are expected to take less than 20 minutes.

Study Visit 3 (Day 2 of Trial). You will return to the study center after an overnight fast for blood collection that corresponds to 24 hours after you ate the test meal. You may then leave the study center. You will need to return at a time that corresponds to 36 hours after eating the test meal, but you do not need to be fasted. Both of the blood collections will be 8 mL each (half a tablespoon) are expected to take less than 20 minutes each.

Study Visit 4 (Day 3 of Trial). You will return to the study center after an overnight fast for blood collection that corresponds to 48 hours after you ate the test meal (8 mL or half a tablespoon of blood will be collected). You may then leave the study center and do not need to return again on this day. This blood collection is expected to take less than 20 minutes.

Study Visit 5 (Day 4 of Trial). You will return to the study center after an overnight fast for blood collection that corresponds to 72 hours after you ate the test meal (8 mL or half a tablespoon of blood will be collected). You may then leave the study center and do not need to return again on this day. This blood collection is expected to take less than 20 minutes.

Blood Sample Storage Agreement
Blood samples collected for this study will be analyzed for glucose, cholesterol, triglyceride, vitamin E, vitamin K, antioxidants (carotenoids and vitamin C), and measures related to inflammation (malondialdehyde). Any remaining samples, including those samples from individuals who do not meet eligibility requirements, will be stored up to 5 years at our study center. We ask that you allow us to store your samples for future analysis specifically related to this study. Storage of samples is completely optional and you may complete the study without agreeing to the storage of samples.

Do you agree to allow us to store any remaining blood samples for additional future measurements? Please circle your response and provide your initials below:

YES NO _____(Participant's Initials) _____Date

4. How long will I be in the study?

You are required to visit the study center briefly at least 12 times per trial, for a total of 73 times to complete all 6 trials. Prior to joining the study, you will complete a screening visit, which will take about 1 hour. Visits in which you pick up food, eat test meals, and have blood collected are expected to take about 20 minutes each. Overall, we anticipate that you will commit about 21 hours over the course of about 12 weeks to complete the study, depending on your availability.

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. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status. If you wish to have your samples destroyed, contact the investigator by phone or email.

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

The primary inconvenience for you is that you must visit our study center briefly 73 times over the course of the entire study. You will need to limit your exercise to less than 7 hours per week throughout the study. Additionally, you may consume only the food and beverage products provided to you for the 3 days prior and during the initial day of the study.

Blood Collection. During the blood drawing aspect of this investigation, only experienced technicians will be responsible for inserting all catheters and needles as well as collecting blood samples. All blood drawing materials will be sterile and sanitary techniques will be used. You may experience a small initial pain from insertion of the needle and bruising may occasionally occur after the procedures are completed. In addition, you may experience lightheadedness or feel faint which is common when people donate blood. During each trial, we will be collecting a total volume of 144 ml (~0.6 cup). Thus, 872 ml (~3.6 cups) of blood will be collected during the entire study (screening + 6 trials) that spans a minimum of 12 weeks. We advise participants not to donate blood and inform their doctor about the study if they need a blood draw at the doctor's office while they are on the study. We do not foresee any additional significant risks with collecting this amount of blood, other than the possible risks stated previously.

Spinach Test Meals. The test meals consist of spinach combined with hardboiled eggs. The spinach for this study will be grown special for this study using water that contains deuterium. Deuterium is a special type of hydrogen that is naturally found in water. It is being used because it is heavier than hydrogen typically found in water. This will allow the spinach to grow and produce vitamin E and vitamin K that contain deuterium. These forms of vitamin E and vitamin K can be measured in your blood after eating the spinach. With our laboratory instruments, we will be able to tell the difference between vitamin E and vitamin K from spinach versus all of the other foods that contain vitamin E and vitamin K from your diet. This allows us to measure absorption of these vitamins with high accuracy. The eggs used in these will be purchased form a local supermarket. There is no risk of eating cooked eggs, no additional risk of eating spinach that is grown with deuterium compared with spinach bought at the store, and no adverse effects are expected.

Confidentiality. To maintain your confidentiality, a number (i.e. code) will be assigned to you. This "code" will only be available to research personnel and any records containing your name will be stored in a locked filing cabinet within a lockable office or on a password protected computer in the principal investigator's laboratory or office. Research personnel under the supervision of the principal investigator and the principal investigator will be the only individuals that have access to this information.

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

Although consumption of eggs with spinach is expected to have a positive effect, there is no guarantee the results will directly benefit you. You will be provided with your screening blood testing results as categorical information, because the results are for research purposes

and cannot be used to provide a clinical diagnosis of disease. In addition, we will provide information regarding your blood pressure, height, weight, waist circumference, and body mass index. If you are interested in learning more about your results during the study, we would be happy to email you a copy of the final study findings that are compiled in an anonymous manner once we have published our findings. Overall, the results obtained from this study are expected to enhance our knowledge of fat from eggs helps to improve the absorption of vitamin E and vitamin K that are naturally found in spinach. This knowledge is of great importance to increase our understanding of the potential health benefits of dietary patterns that link low-fat vegetables with other fat-containing foods to achieve appropriate levels of vitamins in our body.

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 study participation 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;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

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.

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

Yes, they may be used or shared with other researchers without your additional informed consent.

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

There will be no costs for participating in this study except those needed for transportation to and from the OSU campus.

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

By law, payments to participants are considered taxable income. If you complete the study in its entirety and provide all requested blood samples and food-related records, and complete the four 72-hour nutrient absorption trials, you may receive up to $450 (as a check) at the completion of the study. The check will be given at your final study visit. Parking for each visit following acceptance into the study will be paid for by a parking pass. For each of the trials following the informed consent and screening meeting, you will be paid in the following manner:

Trial 1 (Up to a total of $12):

- $1 will be provided for each of the 11 blood collections taking place over 72 hours ($11 total)
- $1 will be provided for food-related records (returning uneaten foods and/or empty containers)

Trial 2 (Up to a total of $23):

- $2 will be provided for each of the 11 blood collections taking place over 72 hours ($22 total)
- $1 will be provided for food-related records (returning uneaten foods and/or empty containers)

Trial 3 (Up to a total of $45):

- $4 will be provided for each of the 11 blood collections taking place over 72 hours ($44 total)
- $1 will be provided for food-related records (returning uneaten foods and/or empty containers)

Trial 4 (Up to a total of $68):

- $6 will be provided for each of the 11 blood collections taking place over 72 hours ($66 total)
- $2 will be provided for food-related records (returning uneaten foods and/or empty containers)

Trial 5 (Up to a total of $90):

- $8 will be provided for each of the 11 blood collections taking place over 72 hours ($88 total)
- $2 will be provided for food-related records (returning uneaten foods and/or empty containers)

Trial 6 (Up to a total of $112):

- $10 will be provided for each of the 11 blood collections taking place over 72 hours ($110 total)
- $2 will be provided for food-related records (returning uneaten foods and/or empty containers)

Study Bonus:
If you complete the entire study and provide all of the requested materials, you will be provided $350 plus a $100 bonus, which will bring your total compensation to $450. This will be given to you in the form of a check. If you withdraw or are dismissed from our study, you will be compensated for the completed aspects as indicated above.

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 Dr. Richard Bruno (Principal Investigator; 614.292.5522; bruno.27@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 Dr. Richard Bruno (Principal Investigator; 614.292.5522; bruno.27@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)**
Relationship to the participant	**AM/PM** **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**

The Ohio State University Consent to Participate in Research

Study Title:	Achieving Nutritional Adequacy Of Vitamins E and K With An Egg/Plant-Based Food Pairing – Study 2
Principal Investigator:	Richard S. Bruno
Sponsor:	Egg Nutrition Center / American Egg Board

- **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.

The purpose of this research is to understand how the absorption of vitamin E and vitamin K found in vegetables like spinach can be improved when eaten along with other foods like eggs that contain fat. If you choose to participate in this study, your involvement would span approximately 8 weeks. During this period, there will be 4 nutrient absorption trials. Each trial would last 72 hours and a trained individual would be collecting blood samples periodically from your arm (11 in total). However, you will be free to come and go from our study center during each trial. The primary risk in this study relates to the small initial pain, bruising, or lightheadedness you may experience during blood collection. There are no costs to you to participate in this research and benefits to you include receiving some of your blood testing results like glucose along with your blood pressure and body mass measurements.

1. Why is this study being done?

Vitamin E and vitamin K are two important nutrients for human health. However, the majority of Americans eat diets that are lacking in these nutrients. In addition, when we eat vegetables containing these high levels of nutrients, their absorption into the body will be poor if sufficient amounts of fat are not eaten along with the vegetables. The combination of a poor diet that is low in vegetables and not eating vegetables with sufficient fat therefore increases the likelihood of having low levels of vitamin E and vitamin K in the body where they are needed to promote health. Studies in humans clearly show that dietary fat is important for the absorption of vitamin E and vitamin K. However, limited information is available to indicate how much fat is optimal and whether fat specifically from eggs can help promote absorption of these nutrients. By successfully completing this study, we expect to demonstrate the benefits of eggs, by way of their fats found in the yolk, to improve the absorption of vitamin E and vitamin K that are naturally present in spinach.

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

Our goal is to recruit healthy 10 men and women between the ages of 18-65 years. To meet this goal, we plan to screen up to 20 individuals.

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

Screening
Before participating in this study, you will need to visit our study center located in 219 Campbell Hall (1787 Neil Ave) on the Ohio State University campus for an initial blood screening to make sure you have fasting blood chemistries (glucose, triglyceride, cholesterol, hematocrit, and hemoglobin) that are consistent with our study criteria. During this time, an experienced technician will measure your blood pressure and collect a small blood sample (2 teaspoons) from your arm. Within a week, we will have determined your blood results, which we will provide to you. If your blood results are consistent with our study criteria, you will be eligible to continue with the study procedures. If not, you will not be able to participate in our study.

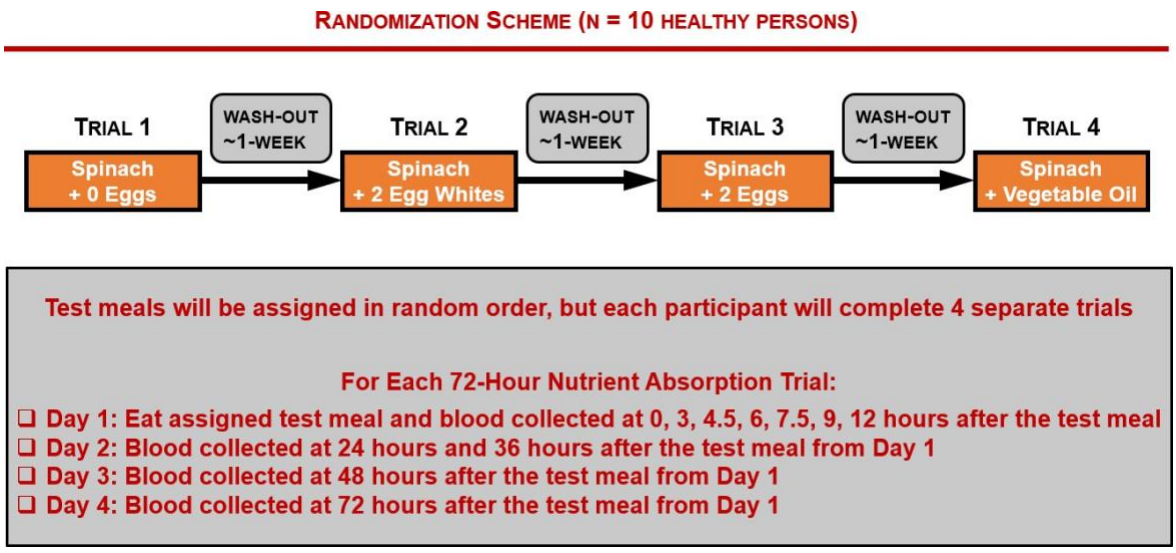
Study Overview
For this study, everyone will complete 4 separate nutrient absorption trials that are separated by at least 1 week. For 3 days prior to each nutrient absorption trial and the first day of each trial, we will be providing all of your foods and beverages. You will eat the same foods for each of the 4 nutrient absorption trials. During each trial, which will be completed over the course of 72 hours, you will receive a test meal containing spinach in combination with eggs or other foods. Each test meal will be assigned by chance, but you will complete all test meals throughout the course of your participation in this study. If you are interested in

learning about the final results of the study, we would be happy to email you a copy of the published study findings.

If you participate in this study, you will be scheduled at your convenience to visit our study center a total of 12 times after the initial screening meeting for the first trial, which includes picking up meals, having your height and weight measured, eating a test meal, and then allowing us to collect blood immediately before eating the test meal and then again at 3, 4.5, 6, 7.5, 9, 12, 24, 36, 48, and 72 hours after eating each test meal. You do not need to remain at our study center during this entire time and are free to leave between each study visit. For the 3 days prior and the first day of the study, we ask that you avoid consuming foods/drinks other than the ones we give to you. The amount of food given will be tailored to your caloric needs so that you maintain the same weight throughout the study. The meals will be cooked and ready to eat; a microwave may be used to reheat food if desired.

Additionally, the menus will be customized to your personal calorie level needed for weight maintenance. It is recommended (but not required) that you eat all that is provided to you so you maintain the same weight throughout the study. It is important to our study that you consume only the foods that we provide and not substitute any other foods without first discussing with the study coordinator. We will also give you a form to record any accidental intake of additional foods/drinks.

We also ask that you do not exercise for more than 7 hours per week throughout the entire study. For each morning visit to our study center, you will need to be fasted for 10-12 hours (no food or drink except for water). Please refer to the picture below for a visual overview of the study.



This study consists of 4 trials that are each 72 hours in duration. For each trial, you will visit the study center once approximately 3 days prior to starting the trial to pick up your foods and beverages. You will then visit the study center 11 times over 72 hours so we can collect a blood sample: 7 times on the first day, 2 times on the second day, 1 time on the third day, and 1 time on the fourth day. During each of these 11 blood draws, we will be collecting approximately 1 tablespoon of blood at first 7 blood draws and 0.5 tablespoon of blood at rest 4 blood collections; or approximately 0.6 cups of blood in total during each nutrient absorption trial. On the first day, you will also eat a test meal containing spinach alone or in combination with whole hardboiled eggs, hardboiled egg whites, or vegetable oil. For each morning visit on day 1, day 2, day 3, and day 4, we ask that you fast overnight for 10 hours, which means eating no foods or beverages other than water. After day 4, you can resume your normal daily activities. After about a week, we would like you to return to the study center to complete Trial 2. After this trial and another period of a week, you will return for Trial 3 and then after another rest period of about a week, you will return to the study center for Trial 4.

The below describes the procedures that will occur during each Trial.

Study Visit 1. This visit occurs approximately 3 days prior to your scheduled 72 hour nutrient absorption trial. Please return to our study center to pick up an insulated cooler containing your foods and beverages for the entire 3 days prior to starting your scheduled trial. This visit will be brief, no blood samples will be collected, and will last less than 15 minutes.

Study Visit 2 (Day 1 of Trial). We ask that you do not consume any food or drink except water for 10-12 hours prior to your study visit. Prior to providing you the test meal, we will measure your height, weight, waist circumference and blood pressure. We will then collect a 16 mL blood sample (1 tablespoon) for your 0 hour blood collection. You will then be asked to eat the test meal within 10 minutes. From that point, we ask that you remain in close proximity to our study center so that you may return for blood collection at 3, 4.5, 6, 7.5, 9, and 12 hours after eating the test meal. For each of these 6 blood draws, we will collect a 16 mL blood sample (1 tablespoon). On this day, we will also provide you lunch and dinner because it is important for our study to control your food intake. Each of the 7 blood collections during this day are expected to take less than 20 minutes.

Study Visit 3 (Day 2 of Trial). You will return to the study center after an overnight fast for blood collection that corresponds to 24 hours after you ate the test meal. You may then leave the study center. You will need to return at a time that corresponds to 36 hours after eating the test meal, but you do not need to be fasted. Both of the blood collections will be 8 mL each (half a tablespoon) are expected to take less than 20 minutes each.

Study Visit 4 (Day 3 of Trial). You will return to the study center after an overnight fast for blood collection that corresponds to 48 hours after you ate the test meal (8 mL or half a tablespoon of blood will be collected). You may then leave the study center and do not need to return again on this day. This blood collection is expected to take less than 20 minutes.

Study Visit 5 (Day 4 of Trial). You will return to the study center after an overnight fast for blood collection that corresponds to 72 hours after you ate the test meal (8 mL or half a tablespoon of blood will be collected). You may then leave the study center and do not need to return again on this day. This blood collection is expected to take less than 20 minutes.

Blood Sample Storage Agreement
Blood samples collected for this study will be analyzed for glucose, cholesterol, triglyceride, vitamin E, vitamin K, antioxidants (carotenoids and vitamin C), and measures related to inflammation (malondialdehyde). Any remaining samples, including those samples from individuals who do not meet eligibility requirements, will be stored up to 5 years at our study center. We ask that you allow us to store your samples for future analysis specifically related to this study. Storage of samples is completely optional and you may complete the study without agreeing to the storage of samples.

Do you agree to allow us to store any remaining blood samples for additional future measurements? Please circle your response and provide your initials below:

YES NO _____(Participant's Initials) _____Date

4. How long will I be in the study?

You are required to visit the study center briefly at least 12 times per trial, for a total of 49 times to complete all 4 trials. Prior to joining the study, you will complete a screening visit, which will take about 1 hour. Visits in which you pick up food, eat test meals, and have blood collected are expected to take about 20 minutes each. Overall, we anticipate that you will commit about 14 hours over the course of about 8 weeks to complete the study, depending on your availability.

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. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status. If you wish to have your samples destroyed, contact the investigator by phone or email.

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

The primary inconvenience for you is that you must visit our study center briefly 49 times over the course of the entire study. You will need to limit your exercise to less than 7 hours per week throughout the study. Additionally, you may consume only the food and beverage products provided to you for the 3 days prior and during the initial day of the study.

Blood Collection. During the blood drawing aspect of this investigation, only experienced technicians will be responsible for inserting all catheters and needles as well as collecting blood samples. All blood drawing materials will be sterile and sanitary techniques will be used. You may experience a small initial pain from insertion of the needle and bruising may occasionally occur after the procedures are completed. In addition, you may experience lightheadedness or feel faint which is common when people donate blood. During each trial, we will be collecting a total volume of 144 ml (~0.6 cup). Thus, 584 ml (~2.4 cups) of blood will be collected during the entire study (screening + 4 trials) that spans a minimum of 8 weeks. We advise participants not to donate blood and inform their doctor about the study if they need a blood draw at the doctor's office while they are on the study. We do not foresee any additional significant risks with collecting this amount of blood, other than the possible risks stated previously.

Spinach Test Meals. The test meals consist of spinach combined with hardboiled eggs. The spinach for this study will be grown special for this study using water that contains deuterium. Deuterium is a special type of hydrogen that is naturally found in water. It is being used because it is heavier than hydrogen typically found in water. This will allow the spinach to grow and produce vitamin E and vitamin K that contain deuterium. These forms of vitamin E and vitamin K can be measured in your blood after eating the spinach. With our laboratory instruments, we will be able to tell the difference between vitamin E and vitamin K from spinach versus all of the other foods that contain vitamin E and vitamin K from your diet. This allows us to measure absorption of these vitamins with high accuracy. The eggs used in these will be purchased form a local supermarket. There is no risk of eating cooked eggs, no additional risk of eating spinach that is grown with deuterium compared with spinach bought at the store, and no adverse effects are expected.

Confidentiality. To maintain your confidentiality, a number (i.e. code) will be assigned to you. This "code" will only be available to research personnel and any records containing your name will be stored in a locked filing cabinet within a lockable office or on a password protected computer in the principal investigator's laboratory or office. Research personnel under the supervision of the principal investigator and the principal investigator will be the only individuals that have access to this information.

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

Although consumption of eggs with spinach is expected to have a positive effect, there is no guarantee the results will directly benefit you. You will be provided with your screening blood testing results as categorical information, because the results are for research purposes and cannot be used to provide a clinical diagnosis of disease. In addition, we will provide information regarding your blood pressure, height, weight, waist circumference, and body mass index. If you are interested in learning more about your results during the study, we would be happy to email you a copy of the final study findings that are compiled in an anonymous manner once we have published our findings. Overall, the results obtained from this study are expected to enhance our knowledge of fat from eggs helps to improve the

absorption of vitamin E and vitamin K that are naturally found in spinach. This knowledge is of great importance to increase our understanding of the potential health benefits of dietary patterns that link low-fat vegetables with other fat-containing foods to achieve appropriate levels of vitamins in our body.

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 study participation 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;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

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.

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

Yes, they may be used or shared with other researchers without your additional informed consent.

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

There will be no costs for participating in this study except those needed for transportation to and from the OSU campus.

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

By law, payments to participants are considered taxable income. If you complete the study in its entirety and provide all requested blood samples and food-related records, and complete the four 72-hour nutrient absorption trials, you may receive up to $250 (as a check) at the completion of the study. The check will be given at your final study visit. Parking for each visit following acceptance into the study will be paid for by a parking pass. For each of the trials following the informed consent and screening meeting, you will be paid in the following manner:

Trial 1 (Up to a total of $12):

- $1 will be provided for each of the 11 blood collections taking place over 72 hours ($11 total)
- $1 will be provided for food-related records (returning uneaten foods and/or empty containers)

Trial 2 (Up to a total of $23):

- $2 will be provided for each of the 11 blood collections taking place over 72 hours ($22 total)
- $1 will be provided for food-related records (returning uneaten foods and/or empty containers)

Trial 3 (Up to a total of $46):

- $4 will be provided for each of the 11 blood collections taking place over 72 hours ($44 total)
- $2 will be provided for food-related records (returning uneaten foods and/or empty containers)

Trial 4 (Up to a total of $69 for grand total of $150):

- $6 will be provided for each of the 9 blood collections taking place over 72 hours ($66 total)
- $3 will be provided for food-related records (returning uneaten foods and/or empty containers)

Study Bonus:
If you complete the entire study and provide all of the requested materials, you will be provided a $100 bonus, which will bring your total compensation to $250. This will be given to you in the form of a check. If you withdraw or are dismissed from our study, you will be compensated for the completed aspects as indicated above.

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 Dr. Richard Bruno (Principal Investigator; 614.292.5522; bruno.27@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 Dr. Richard Bruno (Principal Investigator; 614.292.5522; bruno.27@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)**
Relationship to the participant	**AM/PM** **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**

The Ohio State University Consent to Participate in Research

Study Title:	Achieving Nutritional Adequacy Of Vitamins E and K With An Egg/Plant-Based Food Pairing – Study 3
Principal Investigator:	Richard S. Bruno
Sponsor:	Egg Nutrition Center / American Egg Board

- **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.

The purpose of this research is to understand how the absorption of vitamin E and vitamin K found in vegetables like spinach can be improved when eaten along with other foods like eggs that contain fat. If you choose to participate in this study, your involvement would span approximately 12 weeks. During this period, there will be 6 nutrient absorption trials. Each trial would last 72 hours and a trained individual would be collecting blood samples periodically from your arm (11 in total). However, you will be free to come and go from our study center during each trial. The primary risk in this study relates to the small initial pain, bruising, or lightheadedness you may experience during blood collection. There are no costs to you to participate in this research and benefits to you include receiving some of your blood testing results like glucose along with your blood pressure and body mass measurements.

1. Why is this study being done?

Vitamin E and vitamin K are two important nutrients for human health. However, the majority of Americans eat diets that are lacking in these nutrients. In addition, when we eat vegetables containing these high levels of nutrients, their absorption into the body will be poor if sufficient amounts of fat are not eaten along with the vegetables. The combination of a poor diet that is low in vegetables and not eating vegetables with sufficient fat therefore increases the likelihood of having low levels of vitamin E and vitamin K in the body where they are needed to promote health. Studies in humans clearly show that dietary fat is important for the absorption of vitamin E and vitamin K. However, limited information is available to indicate how much fat is optimal and whether fat specifically from eggs can help promote absorption of these nutrients. By successfully completing this study, we expect to demonstrate the benefits of eggs, by way of their fats found in the yolk, to improve the absorption of vitamin E and vitamin K that are naturally present in spinach.

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

Our goal is to recruit up to 10 healthy men and women between the ages of 18-65 years. To meet this goal, we plan to screen up to 20 individuals.

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

Screening

Before participating in this study, you will need to visit our study center located in 219 Campbell Hall (1787 Neil Ave) on the Ohio State University campus for an initial blood screening to make sure you have fasting blood chemistries (glucose, triglyceride, cholesterol, hematocrit, and hemoglobin) that are consistent with our study criteria. During this time, an experienced technician will measure your blood pressure and collect a small blood sample (2 teaspoons) from your arm. Within a week, we will have determined your blood results, which we will provide to you. If your blood results are consistent with our study criteria, you will be eligible to continue with the study procedures. If not, you will not be able to participate in our study.

Study Overview

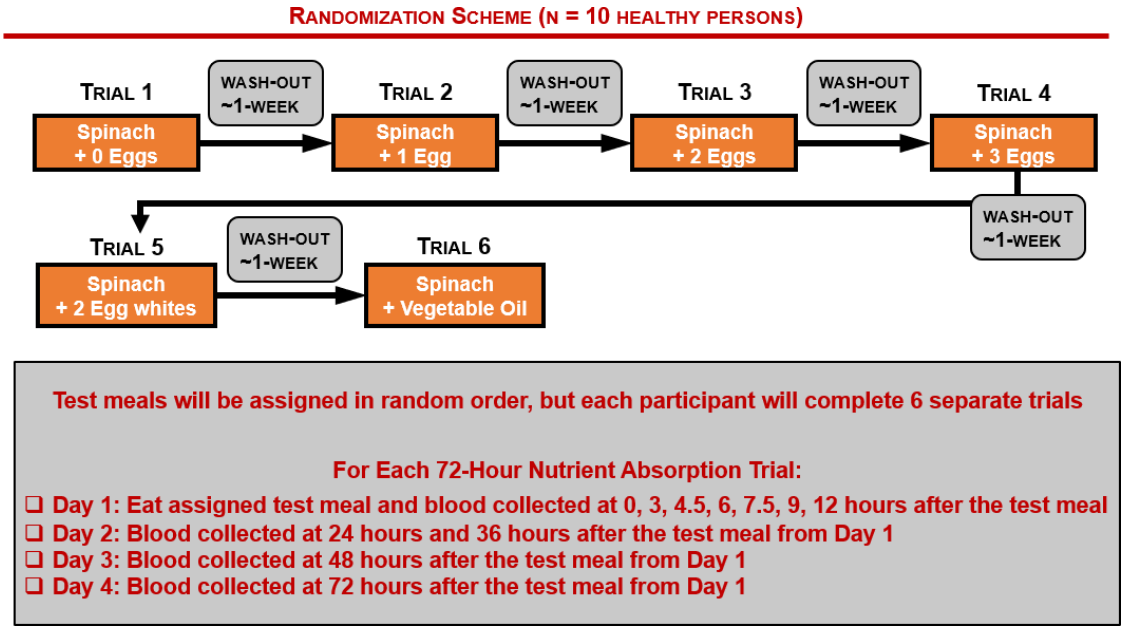
For this study, everyone will complete 6 separate nutrient absorption trials that are separated by at least 1 week. For 3 days prior to each nutrient absorption trial and the first day of each trial, we will be providing all of your foods and beverages. You will eat the same foods for each of the 6 nutrient absorption trials. During each trial, which will be completed over the course of 72 hours, you will receive a test meal containing spinach alone or in combination with eggs or other foods. Each test meal will be assigned by chance, but you will complete all test meals throughout the course of your participation in this study. If you are interested in learning about

the final results of the study, we would be happy to email you a copy of the published study findings.

If you participate in this study, you will be scheduled at your convenience to visit our study center a total of 12 times after the initial screening meeting for the first trial, which includes picking up meals, having your height and weight measured, eating a test meal, and then allowing us to collect blood immediately before eating the test meal and then again at 3, 4.5, 6, 7.5, 9, 12, 24, 36, 48, and 72 hours after eating each test meal. You do not need to remain at our study center during this entire time and are free to leave between each study visit. For the 3 days prior and the first day of the study, we ask that you avoid consuming foods/drinks other than the ones we give to you. The amount of food given will be tailored to your caloric needs so that you maintain the same weight throughout the study. The meals will be cooked and ready to eat; a microwave may be used to reheat food if desired.

Additionally, the menus will be customized to your personal calorie level needed for weight maintenance. It is recommended (but not required) that you eat all that is provided to you so you maintain the same weight throughout the study. It is important to our study that you consume only the foods that we provide and not substitute any other foods without first discussing with the study coordinator. We will also give you a form to record any accidental intake of additional foods/drinks.

We also ask that you do not exercise for more than 7 hours per week throughout the entire study. For each morning visit to our study center, you will need to be fasted for 10-12 hours (no food or drink except for water). Please refer to the picture below for a visual overview of the study.



This study consists of 6 trials that are each 72 hours in duration. For each trial, you will visit the study center once approximately 3 days prior to starting the trial to pick up your foods and beverages. You will then visit the study center 11 times over 72 hours so we can collect a blood sample: 7 times on the first day, 2 times on the second day, 1 time on the third day, and 1 time on the fourth day. During each of these 11 blood draws, we will be collecting approximately 1 tablespoon of blood for each of the first 7 blood draws. For the remaining 4 blood draws, we will be collecting 0.5 tablespoons of blood each time. This will be approximately 0.6 cups of blood in total during each nutrient absorption trial. On the first day, you will also eat a test meal containing spinach alone (Trial 1), spinach with 1, 2, or 3 whole hardboiled eggs (Trials 2-4), spinach with two hardboiled egg whites (Trial 5), or spinach with vegetable oil (Trial 6).

For each morning visit on day 1, day 2, day 3, and day 4, we ask that you fast overnight for 10 hours, which means eating no foods or beverages other than water. After day 4, you can resume your normal daily activities. After about a week, we would like you to return to the study center to complete Trial 2. After this trial and another period of a week, you will return for Trial 3. After Trial 3 and another rest period of a week, you will return for Trial 4. After Trial 4 and another period of one week, you will return for Trial 5, and then after another rest period of about a week, you will return to the study center for Trial 6.

The below describes the procedures that will occur during each Trial.

Study Visit 1. This visit occurs approximately 3 days prior to your scheduled 72 hour nutrient absorption trial. Please return to our study center to pick up an insulated cooler containing your foods and beverages for the entire 3 days prior to starting your scheduled trial. This visit will be brief, no blood samples will be collected, and will last less than 15 minutes.

Study Visit 2 (Day 1 of Trial). We ask that you do not consume any food or drink except water for 10-12 hours prior to your study visit. Prior to providing you the test meal, we will measure your height, weight, waist circumference and blood pressure. We will then collect a 16 mL blood sample (1 tablespoon) for your 0 hour blood collection. You will then be asked to eat the test meal within 10 minutes. From that point, we ask that you remain in close proximity to our study center so that you may return for blood collection at 3, 4.5, 6, 7.5, 9, and 12 hours after eating the test meal. For each of these 6 blood draws, we will collect a 16 mL blood sample (1 tablespoon). On this day, we will also provide you lunch and dinner because it is important for our study to control your food intake. Each of the 7 blood collections during this day are expected to take less than 20 minutes.

Study Visit 3 (Day 2 of Trial). You will return to the study center after an overnight fast for blood collection that corresponds to 24 hours after you ate the test meal. You may then leave the study center. You will need to return at a time that corresponds to 36 hours after eating the test meal, but you do not need to be fasted. Both of the blood collections will be 8 mL each (half a tablespoon) are expected to take less than 20 minutes each.

Study Visit 4 (Day 3 of Trial). You will return to the study center after an overnight fast for blood collection that corresponds to 48 hours after you ate the test meal (8 mL or half a tablespoon of blood will be collected). You may then leave the study center and do not need to return again on this day. This blood collection is expected to take less than 20 minutes.

Study Visit 5 (Day 4 of Trial). You will return to the study center after an overnight fast for blood collection that corresponds to 72 hours after you ate the test meal (8 mL or half a tablespoon of blood will be collected). You may then leave the study center and do not need to return again on this day. This blood collection is expected to take less than 20 minutes.

Blood Sample Storage Agreement

Blood samples collected for this study will be analyzed for glucose, cholesterol, triglyceride, vitamin E, vitamin K, antioxidants (carotenoids and vitamin C), and measures related to inflammation (malondialdehyde). Any remaining samples, including those samples from individuals who do not meet eligibility requirements, will be stored up to 5 years at our study center. We ask that you allow us to store your samples for future analysis specifically related to this study. Storage of samples is completely optional and you may complete the study without agreeing to the storage of samples.

Do you agree to allow us to store any remaining blood samples for additional future measurements? Please circle your response and provide your initials below:

YES NO _____(Participant's Initials) _____Date

4. How long will I be in the study?

You are required to visit the study center briefly at least 12 times per trial, for a total of 73 times to complete all 6 trials. Prior to joining the study, you will complete a screening visit, which will take about 1 hour. Visits in which you pick up food, eat test meals, and have blood collected are expected to take about 20 minutes each. Overall, we anticipate that you will commit about 21 hours over the course of about 12 weeks to complete the study, depending on your availability.

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. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status. If you wish to have your samples destroyed, contact the investigator by phone or email.

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

The primary inconvenience for you is that you must visit our study center briefly 73 times over the course of the entire study. You will need to limit your exercise to less than 7 hours per week throughout the study. Additionally, you may consume only the food and beverage products provided to you for the 3 days prior and during the initial day of the study.

Blood Collection. During the blood drawing aspect of this investigation, only experienced technicians will be responsible for inserting all catheters and needles as well as collecting blood samples. All blood drawing materials will be sterile and sanitary techniques will be used. You may experience a small initial pain from insertion of the needle and bruising may occasionally occur after the procedures are completed. In addition, you may experience lightheadedness or feel faint which is common when people donate blood. During each trial, we will be collecting a total volume of 144 ml (~0.6 cup). Thus, 872 ml (~3.6 cups) of blood will be collected during the entire study (screening + 6 trials) that spans a minimum of 12 weeks. We advise participants not to donate blood and inform their doctor about the study if they need a blood draw at the doctor's office while they are on the study. We do not foresee any additional significant risks with collecting this amount of blood, other than the possible risks stated previously.

Spinach Test Meals. The test meals consist of spinach combined with hardboiled eggs. The spinach for this study will be grown special for this study using water that contains deuterium. Deuterium is a special type of hydrogen that is naturally found in water. It is being used because it is heavier than hydrogen typically found in water. This will allow the spinach to grow and produce vitamin E and vitamin K that contain deuterium. These forms of vitamin E and vitamin K can be measured in your blood after eating the spinach. With our laboratory instruments, we will be able to tell the difference between vitamin E and vitamin K from spinach versus all of the other foods that contain vitamin E and vitamin K from your diet. This allows us to measure absorption of these vitamins with high accuracy. The eggs used in these will be purchased form a local supermarket. There is no risk of eating cooked eggs, no additional risk of eating spinach that is grown with deuterium compared with spinach bought at the store, and no adverse effects are expected.

Confidentiality. To maintain your confidentiality, a number (i.e. code) will be assigned to you. This "code" will only be available to research personnel and any records containing your name will be stored in a locked filing cabinet within a lockable office or on a password protected computer in the principal investigator's laboratory or office. Research personnel under the supervision of the principal investigator and the principal investigator will be the only individuals that have access to this information.

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

Although consumption of eggs with spinach is expected to have a positive effect, there is no guarantee the results will directly benefit you. You will be provided with your screening blood

testing results as categorical information, because the results are for research purposes and cannot be used to provide a clinical diagnosis of disease. In addition, we will provide information regarding your blood pressure, height, weight, waist circumference, and body mass index. If you are interested in learning more about your results during the study, we would be happy to email you a copy of the final study findings that are compiled in an anonymous manner once we have published our findings. Overall, the results obtained from this study are expected to enhance our knowledge of fat from eggs helps to improve the absorption of vitamin E and vitamin K that are naturally found in spinach. This knowledge is of great importance to increase our understanding of the potential health benefits of dietary patterns that link low-fat vegetables with other fat-containing foods to achieve appropriate levels of vitamins in our body.

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).

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.

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.

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

There will be no costs for participating in this study except those needed for transportation to and from the OSU campus.

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

By law, payments to participants are considered taxable income. If you complete the study in its entirety and provide all requested blood samples and food-related records, and complete the four 72-hour nutrient absorption trials, you may receive up to $450 (as a check) at the completion of the study. The check will be given at your final study visit. Parking for each visit following acceptance into the study will be paid for by a parking pass. For each of the trials following the informed consent and screening meeting, you will be paid in the following manner:

Trial 1 (Up to a total of $12):

- $1 will be provided for each of the 11 blood collections taking place over 72 hours ($11 total)
- $1 will be provided for food-related records (returning uneaten foods and/or empty containers)

Trial 2 (Up to a total of $23):

- $2 will be provided for each of the 11 blood collections taking place over 72 hours ($22 total)
- $1 will be provided for food-related records (returning uneaten foods and/or empty containers)

Trial 3 (Up to a total of $45):

- $4 will be provided for each of the 11 blood collections taking place over 72 hours ($44 total)
- $1 will be provided for food-related records (returning uneaten foods and/or empty containers)

Trial 4 (Up to a total of $68):

- $6 will be provided for each of the 11 blood collections taking place over 72 hours ($66 total)
- $2 will be provided for food-related records (returning uneaten foods and/or empty containers)

Trial 5 (Up to a total of $90):

- $8 will be provided for each of the 11 blood collections taking place over 72 hours ($88 total)
- $2 will be provided for food-related records (returning uneaten foods and/or empty containers)

Trial 6 (Up to a total of $112):

- $10 will be provided for each of the 11 blood collections taking place over 72 hours ($110 total)
- $2 will be provided for food-related records (returning uneaten foods and/or empty containers)

Study Bonus:
If you complete the entire study and provide all of the requested materials, you will be provided $350 plus a $100 bonus, which will bring your total compensation to $450. This will be given to you in the form of a check. If you withdraw or are dismissed from our study, you will be compensated for the completed aspects as indicated above.

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 Dr. Richard Bruno (Principal Investigator; 614.292.5522; bruno.27@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 Dr. Richard Bruno (Principal Investigator; 614.292.5522; bruno.27@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**