IRB study code #:1712254
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CONSENT FORM

Study Title: The effects of fermented vegetables on the gut microbiota for prevention of cardiovascular disease

You are invited to participate in a clinical study to assess the role of regular consumption of fermented vegetables on blood substances related to inflammation and how they affect the bacteria that are normally present in your large intestine. You were selected as a possible participant because you are an adult between the ages of 35 to 60 and meet the inclusion criteria for the study as assessed by a screening survey. We ask that you read this form and ask any questions you may have before agreeing to be in the study. This study is being conducted by Dr. Andrea Arikawa, Associate Professor in the department of Nutrition and Dietetics, Brooks College of Health at the University of North Florida, and her doctoral student Melissa Baron.

The purpose of this project is to determine whether regular consumption of fermented vegetables can decrease inflammation and change the types of bacteria that are normally present in your large intestine. Recent research studies have linked the gut bacteria to many disorders and conditions, such as obesity, cardiovascular disease, diabetes, etc. We also know that certain bacteria are considered probiotic bacteria because they contribute to a healthy gut, while others have been associated with inflammation and disease. Fermented foods may contain beneficial bacteria that may improve health in humans. However, there is a lack of research studies examining the effects of regular consumption of fermented foods on health. This study will help us better understand if regular consumption of fermented vegetables can improve inflammation and change the gut bacteria towards a more beneficial profile.

What is fermentation?
Fermentation is when bacteria use food components for their own needs while making other components that can change the taste and texture of foods. Lactic acid fermentation is a process by which bacteria convert sugars that are naturally present in foods into lactic acid, which is a substance that gives fermented foods their acidic taste. The primary types of bacteria that are able to do this are Lactobacilli and Bifidobacteria.

Are the bacteria present in fermented vegetables good for health?
Research studies, particularly those conducted in Asian countries where the consumption of fermented vegetables is much higher than in the U.S., suggest that the consumption of fermented vegetables is associated with several health benefits such as prevention of high blood pressure and heart disease, prevention of weight gain, protection against gastrointestinal disorders and diabetes.

Study Procedures:
We will recruit 90-100 participants for this study. Eligible participants will be randomly placed into one of two groups: a control group who will receive print materials about a heart-healthy diet and continue to follow their normal diet for 8 weeks, and a fermented vegetable group who will be asked to consume 100 grams or 1/2 cup of fermented vegetables at least 5 days per week for 8 weeks. All vegetables will be provided by the study. If you agree to be in this study, you have an equal chance of being placed in one of the two groups. Therefore, you need to be willing

to be part of ANY of the two groups.

If you agree to be in this study, we will ask you to do the following things:

1. Carefully read this consent form and talk to a study staff member over the phone or in person about the details of this study and ask any questions you may have about the study. You will be given the opportunity to sign the consent form during your first study visit.
2. Go to the Brooks College of Health twice during a period of 8 weeks**,** during the morning hours, for blood and stool collection. These visits will last approximately 45 minutes.
3. Fill out online surveys that will take approximately three hours during the 8-week study period.

Here is the list of measurements and/or data to be collected during each of the two study visits:

- Body weight
- Height
- Body fat percentage
- Blood pressure
- Blood draw of 10 mLs (approximately 2 tablespoons) to measure blood markers associated with inflammation and cardiovascular disease
- Three stool samples

Here is the list of measurements and/or data to be collected from the online surveys:

Survey	When to complete	Estimated time to complete
Diet history questionnaire	Before first clinic visit	30 min each (total = 60 min)
Demographics	Before first clinic visit	2 minutes
Medical history	Before first and second clinic visit	10 min each (total = 20 min)
24-hr diet recall (to be completed with study staff)	During first clinic visit, at 4 weeks (by phone) and during second clinic visit	20 min each (total = 60 min)
Physical activity survey	Before first and second clinic visit	10 min each (total = 20 min)
Symptoms log	Weekly during the study	2 min each (total = 16 min)

Detailed description of treatment group

If you are placed in the fermented vegetable group, you will receive 700 grams of vegetables per week for 8 weeks. At your first study visit, we will give you four weeks' supply of the vegetables in a large sealed container with a measuring cup. You will be asked to consume one measuring cup per day of the fermented vegetables provided. It is important that you like and be willing to consume these vegetables during the 8 weeks of the study.

Symptoms log

All participants will be filling out symptoms logs weekly to report any gastrointestinal issues that may arise during the study. These logs will help us monitor any side effects that may result from consumption of the vegetables provided by the study, such as bloating, abdominal pain, and swelling. It is important the participants placed in the control group also fill out these logs, so that we can compare the frequency of symptoms reported between the two groups. Participants

placed in the fermented vegetable group will also be asked to report weekly consumption of the study vegetables in these logs.

Detailed Description of study visits
Your first study visit will be scheduled after the orientation session and the second study visit will be scheduled 8 weeks after the first study visit. These visits will take approximately 45 minutes and you will be asked to schedule them in the morning because you will need to be fasting for the blood draw. Skilled nurses will collect approximately 4 tablespoons of your blood using sterilized needles that will be immediately disposed of following blood collection. During these visits we will also measure your body weight, height, body fat percentage, blood pressure and we will ask you about your food intake during the previous day. You will also be asked to bring three stool samples collected prior to the study visit. Immediately after consenting to be in the study and within one week of your scheduled study visit, you will receive a kit for collection of the stool samples, with instructions. You will be asked to collect three stool samples on three separate days and to bring these samples to your study visit.

Other procedures:
There will be several online surveys that you will be asked to fill out following your study visits. We ask you to fill those out within one week of your study visit. Study staff will be contacting you four weeks after your first study visit, to ask about your food and beverage intake during the previous 24 hours. You will receive weekly reminders from study staff to fill out the symptoms log.

Risks of Being in the Study:
There is a small risk of infection when blood is taken, but the risk is minimal as all needles and equipment are sterilized and the procedures are performed by skilled phlebotomists. You may experience some mild to moderate pain lasting a few seconds upon insertion of the needle used to draw the blood. You may also get a bruise from the blood draw. There is also a small chance that you will experience some psychological distress when filling out some of the surveys. You may choose not to answer any questions that may make you feel uncomfortable or you may choose to not participate in the study at any time. Intake of the fermented vegetables may lead to excessive gas formation and bloating, which could cause discomfort. If you experience some of these side effects, please contact study staff to talk about possible ways to resolve these issues.

Benefits of Being in the Study:
The benefits to participation include materials about a heart-healthy diet and free supply of vegetables for those in the vegetable group.

Compensation:
You will receive a total of $120 for participation in this study as follows:
<u>First study visit</u> ($40)

- 3 stool samples: $15
- Food surveys: online survey and in-person survey for $10
- Blood sample and body composition measurements: $15

<u>Second study visit</u> ($80)

- 3 stool samples: $15
- Food surveys: online survey, phone survey at 4 weeks and in-person surveys for $15
- Blood sample and body composition measurements: $30

Parking:
Parking will be paid by the study for the two study visits. Information about parking will be sent to study participants 48 hours prior to the scheduled study visits.

Care in the case of injury:
In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. If you think that you have suffered a research related injury let the principal investigator or co-investigator know right away (Dr. Andrea Arikawa (phone: (904) 479-8995, email: andrea.arikawa@unf.edu) or Melissa Baron (phone: (904) 620-5282, e-mail: melissa.baron@unf.edu).

Confidentiality:
The information provided by you and the information taken from the measurements of your body will be held strictly confidential and used for the purposes of research only. All of the study staff has completed the federally required training with regard to confidentiality of health information in research, and any/all medical information gathered, test results, lab samples will NOT have your name on them. Instead, they will be labeled with a study ID number only. Your name will be associated with your study ID number on one list, to be kept in Dr. Arikawa's password protected office computer. In addition, all data will be stored in a secure server housed by the University of North Florida. Your study ID number will appear on all other study records. All your study records will be kept private, in a locked file cabinet in Dr. Arikawa's office, for access to the study investigators and research staff. The UNF Institutional Review Board and federal representatives might also have access to your files in case of an audit. None of your information will ever be given to anyone, and we will not include any information that will make it possible to identify you as a subject of this study in any sort of report we might publish.

With regard to your blood and stool samples, they will be stored in a -60ºC freezer in room 3002, in building 39. These samples will have your study ID on them and the date on which the specimens were collected. Your name will NOT be stored with your biological samples. We will store these samples for up to five years after the study is over. The freezer in which they are stored is kept behind a locked door. The only people who have access to this freezer are research staff who have all been through the federally required training with regard to confidentiality of health information in research. The purpose for storing these samples is to enable us to conduct additional analyses in the samples as funding and new information regarding the benefits of fermented foods becomes available. The principal investigator will maintain ownership of these samples while they are stored. You will not receive any results from future tests conducted with these stored samples.

The storage of your blood samples beyond the end of the study is optional. Please indicate here with your initials whether you consent to allow us to store your blood samples beyond the end of

the study. Your willingness to do this will not impact whether you will be allowed to participate in the rest of the study.

Yes, I consent to allow my **blood** samples to be stored beyond the end of the study _____

No, I do not consent to allow my **blood** samples to be stored beyond the end of the study _____

Voluntary Nature of the Study:
Your decision whether or not to participate will not affect your current or future relations with the University. If you decide to participate, you are free to withdraw at any time without affecting those relationships. The procedure to withdraw is to email Dr. Andrea Arikawa at andrea.arikawa@unf.edu or Melissa Baron at melissa.baron@unf.edu and inform one of them that you wish to withdraw from the study. You may also withdraw by emailing the study email address at happygut@unf.edu.

The principal investigator may stop this research or your participation in it at any time. This may be done for several reasons, such as administrative issues, equipment issues, or health concerns, and it does not require your agreement.

Contacts and Questions:
The researchers conducting this study are Dr. Andrea Arikawa, PhD, RD, LD/N (principal investigator), and Melissa Baron, MS, RD, LD/N. You may ask any questions you have now. If you have questions later, you may contact Melissa Baron at Melissa.Baron@unf.edu, phone: (904) 620-5282, or Dr. Arikawa in the Department of Nutrition & Dietetics, University of North Florida, 1 UNF Drive, Jacksonville, FL 32224. Phone: 904-479-8995; email: Andrea.Arikawa@unf.edu.

Study website: https://happygut.domains.unf.edu/

If you have any questions or concerns regarding the study and would like to talk to someone other than the researcher(s), please contact UNF Institutional Review Board at (904) 620-2498 or at the email: irb@unf.edu.

You will be given a copy of this form to keep for your records.

Statement of Consent:
I have read the above information. I have asked questions and have received answers. I consent to participate in the study.

Name (please print)_____

Signature _____ Date _____

Signature of Investigator _____ Date _____