IRB study code #:10334264-7
Version: 07/05/2019

# CONSENT FORM

**Study Title: Effects of fermented vegetables on markers of inflammation and composition of the intestinal microflora in women**

You are invited to be in this Fermented Vegetable study to look at how eating fermented vegetables affects some blood substances related to inflammation and how it affects the bacteria that are normally present in your large intestine. You were selected as a possible participant because you are a female between the ages of 18 to 70 and meet the requirements 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, who is an Assistant Professor in the department of Nutrition and Dietetics, Brooks College of Health at the University of North Florida.

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 a wide range of 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 to include more beneficial bacteria and less harmful bacteria.

**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.

**What is the purpose of lactic acid fermentation?**
Lactic acid fermentation can be used to make yogurt from milk but when applied to vegetables, it can increase their shelf life by increasing the acidity of the vegetables, which blocks the growth of microorganisms that spoil foods.

**What is the difference between a fermented vegetable and a non-fermented vegetable?**
A fermented vegetable tastes more acidic and contains live bacteria, which are the ones responsible for the acidic taste. A non-fermented vegetable does not have an acidic taste and although it also contains live bacteria, the amount of bacteria present is much lower compared to a fermented vegetable.

**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 39 women for this study. Participants will be recruited by posting flyers throughout Jacksonville, including Women's clinics and the UNF Women's Center and also by newspaper advertisements. Eligible participants will be placed into one of 3 groups: a control group who will continue to follow their normal diet for the study period of 6 weeks, a non-fermented vegetable group who will be asked to consume 1/2 cup of non-fermented vegetables every day for 6 weeks, and a fermented vegetable group who will be asked to consume 1/2 cup of fermented vegetables every day for 6 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 three groups. Therefore, you need to be willing to be part of ANY of the three 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 if you meet with a study staff in person or sign it at the study visit if your initial conversation with study staff is over the phone.
2. Go to the Brooks College of Health twice during a period of 6 weeks**,** during the morning hours, for data collection that will last approximately 30 minutes.
3. Fill out online/paper surveys twice during the 6-week study period.

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

- Body weight
- Height
- Body fat percentage
- Blood pressure
- Pulse
- Blood draw of 10 mLs (approximately 2 tablespoons) to measure insulin levels, and two inflammatory markers, C-reactive protein and lipopolysaccharide
- First morning urine sample to measure F2-isoprostanes and creatinine
- Stool sample

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

- Dietary intake
- Demographics
- Physical activity
- Prescription medication use
- Gastrointestinal function
- Vegetable intake side effects logs for those in the vegetable groups

*Detailed Description of vegetable groups*

If you are placed in a group that will consume fermented or non-fermented vegetables you will receive 4 cups of vegetables per week for 6 weeks. At your baseline appointment, we will give you two weeks' supply of the vegetables that will be packaged in 1-cup deli containers. Therefore, at your baseline appointment, you will receive a bag with 8 one-cup deli containers. Every other week, we will deliver to you a new bag with another 8 one-cup deli containers. These containers must be refrigerated and you should consume half a cup (1/2 the deli container) every day. You will be receiving two types of vegetables to add variety. There will be a mix of carrots with dill sauerkraut and pickles. It is important that you like and be willing to consume these vegetables during the 6 weeks of the intervention.

*Gastrointestinal function and side effects log*
All participants will be filling out logs 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, as well as compliance with the intervention. These logs will be collected by study staff every week, at the time of delivery of the vegetables.

*Detailed Description of study visits*
Your first study visit will be scheduled after the orientation session and the second study visit will be scheduled 6 weeks after the first study visit. These visits will take approximately 30 minutes and you will be asked to schedule them in the morning because you will need to be fasting for the blood draw. Skilled phlebotomists will collect approximately 2 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, pulse, blood pressure and we will ask you to bring a urine sample and a stool sample. The urine sample must be the first morning urine of the day of your appointment. The stool sample should be collected within 24 hours of the study visit. You will receive all materials necessary for the specimen collections at the orientation session.

*Other procedures:*
There will be several online and paper 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. The gastrointestinal function survey should be completed daily and the vegetable intake side effects logs should be filled out every week only by participants who are randomized into the vegetable groups.

**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. You may also 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 free supply of vegetables for those in the vegetable groups and written reports regarding your body fat percentage and C-reactive protein (an inflammatory marker). This information will be provided AFTER all data collection for the study is completed.

**Compensation:**
You will receive a total of $30 for participation in this study as follows:

- $10 upon completion of baseline data collection
- $10 at the 4-week time point counting from the date of your baseline appointment.
- $10 upon completion of the follow-up data collection

**Parking:**
Parking will be paid by the study for the orientation, baseline and follow up 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) 620-1433, email: andrea.arikawa@unf.edu) or Dr. Michele Bednarzyk (phone: (904) 620-2684, e-mail: mbednarz@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. Once you have turned in any forms with your name on them and they are reviewed as being complete, your name will be removed by whiting out your name and photocopying the form so that only your ID number remains. 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 your name will never be associated with your records on paper or on computer. In any sort of report we might publish, we will not include any information that will make it possible to identify you as a subject of this study.

With regard to your blood, urine and stool samples, they will be stored in a -70ºC 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 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 and urine 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, urine, and stool 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 _____

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

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

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

No, I do not consent to allow my **urine** 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 and inform her that you wish to withdraw from the study. You may also withdraw by emailing the study email address at ferveggie@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 Andrea Arikawa, PhD (principal investigator). You may ask any questions you have now. If you have questions later, you may contact Dr. Arikawa at the Department of Nutrition & Dietetics, University of North Florida, 1 UNF Drive, Jacksonville, FL 32224. Phone: 612-620-1433; email: andrea.arikawa@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 _____