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INSTITUTE OF AGRICULTURE AND NATURAL RESOURCES
COLLEGE OF AGRICULTURAL SCIENCES AND NATURAL RESOURCES
DEPARTMENT OF FOOD SCIENCE AND TECHNOLOGY

INFORMED CONSENT FORM

IRB# (Labeled by IRB)

Project: Promoting gastrointestinal health and reducing subclinical inflammation in obese individuals through intake of whole wheat products in comparison with fruits and vegetables

Purpose of the Research

The purpose of this research is to demonstrate that the bacteria that live in our digestive tract are important contributors to the health benefits of fruits, vegetables, and whole grain foods. To participate, you must meet the following criteria:

- x Have no known gastrointestinal diseases
- x If a student, you will not graduate before Aug 2015
- x Be 19 years of age or older
- x Have not taken antibiotics within the last 6 months
- x Participate in less than 1 hour of structured exercise per week
- x Have a "low" typical intake of fruits, vegetables, and whole grains
- x Have no known allergies to fruits, vegetables, or grains
- x Have a body mass index above 25
- x Be willing to adhere to intervention instructions (either consume 5 servings of fruits and vegetables per day or 3 servings of whole grain foods per day)
- x Be willing to provide 2 stool samples and 2 blood samples to study personnel
- x Be willing to complete 2 diet history questionnaires online
- x Be willing to fill out a gastrointestinal symptom questionnaire weekly during the study
- x Be willing to keep track of consumption of test foods on a daily basis

Procedures

During recruitment, you will be asked to complete a diet history questionnaire online as part of the screening process. This questionnaire takes about 1 h and can be filled out at any time on any computer that is connected to the internet. You will receive instructions on how to complete this questionnaire. If your dietary analysis meets the inclusion criteria you may be invited to participate in the study.

Subjects that meet the inclusion criteria and consent to being involved in the study will be required to visit the study facility 6 times (weeks -1, 0, 1, 2, 3, and 4). At the study facility visit subjects will collect and turn in diet records and gastrointestinal symptom questionnaires and order and pick up food items. At weeks -1 and 3, subjects will also receive stool collection kits to turn in at the clinical facility visits (described below). Each study visit will take about 20 min. During this 20 min, subjects will turn in diet records and GI symptom questionnaires. They will also pick up food items ordered the previous week and order food items for the next week. They will also have a chance to speak with the study personnel about any concerns. On visits -1 and 3, subjects will also receive stool collections kits with instructions on how to use them. During

week 4 of the study, subjects will also be instructed to complete a second diet history questionnaire (identical to that completed during recruitment).

The food diary requires writing down all of the fruits, vegetables, and whole grain products consumed every day. There is a form supplied to help with this. For fruits and vegetables, you should write down the form (whole, peeled, juice, cooked, raw, etc.) that they were consumed in addition to the amount. For whole grains, you should write down the type of food and brand as well as the amount consumed.

Subjects will be required to visit the clinical facility 2 times (weeks 0 and 4). At the clinical facility visit, subjects will be fasted (12 h fast) and a blood sample will be taken by a licensed phlebotomist using standard venipuncture techniques. Weight and height will be recorded. Subjects will give their stool sample to the study personnel either already collected or collected at the facility. If the subjects is unable to defecate at either of these times, they will be instructed to contact the study personnel as soon as possible after the visit to have the stool sample picked up.

Total estimated time for participation in this study is 6 hours over the course of 5 weeks (six 20 minute study facility visits; two 30 minute clinical facility visits; two 60 minute diet history questionnaires; 60 minutes cumulative time filling out dietary records and GI symptom questionnaires).

Risks and/or Discomforts
You may experience gastrointestinal discomfort from consuming fruits and vegetables or whole grains if you are not used to consuming these products normally. This will be monitored through gastrointestinal symptom diaries that you will be fill out. Typically, the discomfort will subside within days. If you wish to withdraw from the study due to gastrointestinal discomfort please inform the study personnel immediately. This will not harm your relationship with the researchers.

You may also experience some discomfort during blood draw. Additional risks during blood draw include bruising, infection, and dizziness. Standard procedures will be used to minimize discomfort.

You may also feel somewhat awkward or embarrassed when providing a stool sample. Stools will be collected privately using a stool collection kit that fits on the toilet seat. This kit contains a removable opaque container with a lid, so the specimen can be transported discretely. You will have the option of collecting the stool at home or at the clinical facility.

If you are concerned about any physical distress experienced during the study, please consult with your regular medical provider.

Benefits
By following the procedures in this study, members of the treatment groups will meet the recommended intakes of fruits and vegetables or whole grains. Any benefits arising from meeting the USDAs recommended servings of these foods may be realized in this study.

You will also receive a copy of your dietary analysis along with the findings from the blood tests at the end of the study. This will show intake of nutrients and food groups. You can also request the findings from your blood tests, which include fasting blood glucose, cholesterol, LDL cholesterol (bad cholesterol), HDL cholesterol (good cholesterol), triglycerides, and the

inflammatory markers IL-6, C-reactive protein, and lipopolysaccharide binding protein. These results of the tests and analysis should be interpreted by your primary care physician.

Benefits to others include new evidence in support of fruits and vegetables and whole grain in the diet for prevention of inflammation and reduction of risk factors of many diseases. This project could lead to improved understanding of how diet mediates an anti-inflammatory effect, allowing health professionals to offer better suggestions to individuals on how to make the most positive impact on health through diet. Due to the rising problems associated with consumer health, this project has the potential to have a positive impact on the well-being of many individuals.

Confidentiality
Only the lead investigators on the project will have access to the personal information you provide. At the end of the study, biological samples and contact information will be destroyed. No names or phone numbers will be reported or provided to the sponsor of this research or any other entity other than the study personnel.

To maintain confidentiality, you will receive a 3 digit ID number that will be used throughout the study, to be used on sample containers, test tubes, and data reports. You should remember this number.

Compensation
You will receive [redacted] for completing the diet history questionnaire (which takes 45 min). You will receive [redacted] if you meet the inclusion criteria, are enrolled in the study, and complete study tasks. If you are enrolled but withdraw before the end of the study you will receive [redacted]. You will receive this compensation by contacting Julianne Kopf (402-801-2006). Upon receipt, you will be required to fill out a research participant disclosure form. If you will be receiving [redacted] this form includes your social security number for tax purposes.

Opportunity to Ask Questions
You may ask any questions concerning this research and have those questions answered before agreeing to participate in or during the study. Please contact the investigator (drose3@unl.edu; 402-472-2802):

- x if you want to voice concerns or complaints about the research
- x in the event of a research related injury

Participant's initials _____

Please contact the University of Nebraska-Lincoln Institutional Review Board (402-472-6965) for the following reasons:

- x you wish to talk to someone other than the research staff to obtain answers to questions about your rights as a research participant
- x to voice concerns or complaints about the research
- x to provide input concerning the research process
- x in the event the study staff could not be reached

Freedom to Withdraw
Participation in this study is voluntary. You can refuse to participate or withdraw at any time without harming your relationship with the researchers or the University of Nebraska-Lincoln. If you withdraw you will not receive a penalty or loss of benefits to which you are otherwise entitled.

Consent, Right to Receive a Copy
You are voluntarily making a decision whether or not to participate in this research study. You will be given a copy of this consent form to keep.

Printed name: _____

Signature: _____ Date: _____

Investigators and contact information

Julianne Kopf, primary contact 402- 801-2006 juliannekopf@gmail.com
Devin J. Rose, secondary contact 402-472-2802 drose3@unl.edu