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GRAND FORKS HUMAN NUTRITION RESEARCH CENTER
CONSENT TO PARTICIPATE IN RESEARCH

Project Title: Traditional Indigenous Foods diet and health study

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Department: USDA-ARS Grand Forks Human Nutrition Research Center (GFHNRC)

What should I know about this research?
- Someone will explain this research to you.
- Taking part in this research is voluntary. Whether you take part is up to you.
- If you don't take part, it won't be held against you.
- You can take part now and later drop out, and it won't be held against you.
- If you don't understand, ask questions.
- Ask all the questions you want before you decide.

How long will I be in this research?
We expect that your taking part in this research will last about 8 weeks. Then, an additional debriefing appointment will be held at the end of the study.

Why is this research being done?
The purpose of this research is to study the effects of a diet based on traditional indigenous foods of Great Plains Indians has on activity, mood, and health markers of American Indians.

What happens to me if I agree to take part in this research?
The protocol, study purpose, and what is required of you during the study will be explained to you at your initial visit (this visit). You will be asked to sign this consent form to agree to your voluntary participation in the study. You will fill out a W-9 for payment to be made. You will complete the Physical Activity Readiness Questionnaire (PAR-Q+). You will be shown where to access the questionnaires online, how to fill out the questionnaires, how to fill out the food diary and how to use the accelerometer. A second appointment will be scheduled and the day before that appointment you will be asked to fast overnight. You will come in for the second appointment for a fasting blood draw, height, weight, BMI, and blood pressure.

<u>Inclusion Criteria</u>
- American Indian
- 18 to 55 years of age
- Reliable transportation to GFHNRC

Date: _____
Subject Initials: _____

Exclusion Criteria

- Health condition that impairs mobility or ability to safely be physically active
- Fasting Blood glucose > 130 mg/dl
- Currently taking anti-inflammatory medications
- Pregnant, breast feeding or lactating
- Currently on a regulated diet
- Currently exercising for 60 min or longer greater than 2 times per week
- Allergic to any of the study foods shown in the menu and list of ingredients
- Strong aversion to any of the study foods
- Taking one of the following medications: blood thinning drugs, insulin, biologics, chemotherapy or on immune suppressant medications, and those who have started a new hyperglycemic, hypercholesterolemia, anti-depressant, anti-anxiety, or anti-psychotic medication(s) in the last two months.

Eligibility will be determined by use of the PAR-Q+, BMI, blood pressure, and fasting blood draw results. If you are not eligible, we will contact you by letter or email. If you are eligible, we will contact you for a start date.

During the Study:

The study will use an ABAB design. During Phase A you will eat your usual diet. During Phase B you will eat only the Traditional Indigenous Foods that we will provide to you. You will start the study on Phase A1, then you will switch to Phase B1. You will go back to eating your usual diet (Phase A2), and then switch back to eating the Traditional Indigenous Foods diet (Phase B2). The study will last about 8 weeks plus one final debriefing visit.

- **Blood Draw Visit-** You will be asked to fast one night. The next day you will visit the GFHNRC to be measured for weight, blood pressure and for fasting morning blood draw.
    a. You will have your blood drawn by a nurse at the GFHNRC as part of the eligibility screening and near the end of each phase for a total of 5 times. The blood will be analyzed for calcium, glucose, and lipids (triglycerides and cholesterol panel). It will also be looked at for a complete blood count and for signs of inflammation.
- **Accelerometer**- You will come to the GFHNRC to pick up an accelerometer to wear for the last 7 days of each phase and return it at your next visit to GFHNRC.
- **Food Diary**- You will fill out a food diary to document three days of your usual diet. You will need to do this in both Phase A1 and Phase A2 of the study.
- **MHS Questionnaires**- You will fill out questionnaires about your mood, happiness, and stress. These will be filled out five times during each of the 4 phases.
- **S-E and S-R Questionnaires**- You will fill out questionnaires on self-efficacy and self-regulation of eating and physical activity once at the end of each of the four phases.

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- **TIF diet-** Monday thru Friday you will come to the GFHNRC to pick up a provided cooler with the meals from the Traditional Indigenous Foods diet and a brief daily diet compliance questionnaire to be filled out and returned with the cooler.
- **FL Questionnaires-** You will fill out food liking Questionnaires for three meals (breakfast, lunch, and supper) from the Traditional Indigenous Foods diet (provided in the cooler) twice for each meal during Phase B1 and B2. Four times total during the study for each meal.
- **Contact-** The PI or GFHNRC staff may contact you to remind you to do the questionnaires and complete the food diary.
- **You are free to skip any of the questions on any of the Questionnaires that you would prefer not to answer.**

Summary of what you will do during each phase.

- Phase A1 (Your usual diet): 10 to 14 days long; Food Diary; Contact; MHS Questionnaires; S-E and S-R Questionnaires; Accelerometer; and Blood Draw Visit.
- Phase B1 (Traditional Indigenous Foods diet): 10 to 24 days long; TIF diet; Contact; MHS Questionnaires; S-E and S-R Questionnaires; FL Questionnaires; and Blood Draw Visit.
- Phase A2 (Your usual diet): 10 to 24 days long; Food Diary; Contact; MHS Questionnaires; S-E and S-R Questionnaire; Accelerometer; and Blood Draw Visit.
- Phase B2 (Traditional Indigenous Foods diet): 10 to 24 days long; TIF diet; Contact; MHS Questionnaires; S-E and S-R Questionnaires; FL Questionnaires; and Blood Draw Visit.

You will be scheduled to come in for a debriefing visit in which you will return the accelerometer, fill out a final questionnaire and provide any comments you have about the study.

Could being in this research hurt me?
The most important risks or discomforts that you may expect from taking part in this research include:

Allergic reaction: The menu is composed of foods that you may have had little or no experience with consuming. You may have an allergic reaction to a food or develop an allergy while eating the Traditional Indigenous Foods diet. You will be shown the menu before signing the consent form to verify that you are not allergic to any of the food in the Traditional Indigenous Foods diet. If you develop any allergic response while on the Traditional Indigenous Foods diet, you should stop eating the diet and seek medical attention.

Low Calcium: The Traditional Indigenous Foods diet may have lower calcium content due to the lack of dairy products. We will monitor your blood calcium levels during the blood draws. If your calcium concentration is too low after consuming the Traditional Indigenous Foods diet, then we will work with the GFHNRC consultant physician (Dr. Eric Johnson) regarding the GFHNRC providing you with oral calcium tablets (calcium carbonate) to increase your blood calcium levels.

Blood draw Risks: You will have blood drawn five times during the study, no more than 15 milliliters per draw (about a tablespoon). No more than 75 milliliters will be drawn over the 8-week period, in comparison blood banks donations are limited to 475 milliliters every 8 weeks. During the blood draw the participants may have a feeling of mild discomfort which can include redness, swelling and bruising at the draw site. They may also feel lightheaded during blood draw. Since blood draw does puncture the skin there is a chance of infection.

Questionnaires: There is no risk associated with answering the questions on the questionnaires. However, you may feel uncomfortable answering some of the questions. If there are questions you do not want to answer, you may skip those questions.

Will being in this research benefit me?
You may not benefit personally from being in this study, but we hope that in the future others may benefit from our findings.

How many people will participate in this research?
Approximately 15 people will take part in this study at the GFHNRC.

Will it cost me money to take part in this research?
You will not have any costs for being in this research study. But you must have access to the internet. You also need a desktop or laptop computer, smartphone, or tablet on which to complete questionnaires required by this study. You will have to provide your transportation to and from the GFHNRC for food pick-up, blood draw, screening and debriefing visits. Also, we do not withhold income, social security, unemployment taxes, or any other taxes. You may have to pay income taxes on the money you receive. All tax questions relating to the taxability of the payment should be directed to your personal tax accountant or to your local Internal Revenue Service Office.

Will I be paid for taking part in this research?
You will be paid for being in this research study. After you finish the study, you will be reimbursed $1610 or a 38-month individual membership or 27-month family membership to Choice Health & Fitness. If you had a blood draw during your eligibility screening and found ineligible, you will be paid $25. If you drop out of the study, you will be paid a prorated amount for the procedures you completed.

Who is funding this research?
The United States Department of Agriculture (USDA) is funding this research study. This means that the Grand Forks Human Nutrition Research Center is receiving payments from the USDA to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or an increase in salary from the USDA for conducting this study.

Date: _____
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What happens to information collected for this research?
Your private information may be shared with individuals and organizations that conduct or watch over this research, including:

- The USDA, as specified in the USDA/ARS Privacy Act System of Records
- Study personnel who work at the Grand Forks Human Nutrition Research Center
- The Institutional Review Board (IRB) that reviewed this research
- The Supervising Physician at the UND School of Medicine and Health Sciences
- As required by law or court order

We may publish the results of this research. However, we will keep your name and other identifying information confidential. We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy.

Data or specimens collected in this research will not be used or distributed for future research studies, even if identifiers are removed. If you would prefer to have your blood samples returned back to you, please make this request here (Please circle one):

YES --- I would like my blood samples returned to me and I acknowledge I will need to pick up what remains of the samples from the USDA Grand Forks Human Nutrition Research Center.

NO --- I do not want my blood samples returned and I acknowledge they will be disposed of once the needs of this research study are completed.

Could being in this research hurt me?
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. Payment for any such treatment is to be provided by you (you will be billed) or your third-party payer, if any (such as health insurance, Medicare, etc.). No funds have been set aside to compensate you in the event of injury. Also, the study staff cannot be responsible if you knowingly and willingly disregard the directions they give you. If you are injured while taking part in this research project as a result of the negligence of a United States Government employee who is involved in this research project, you may be able to be compensated for your injury in accordance with the requirements of the Federal Tort Claims Act. Compensation from individuals or organizations other than the United States might also be available to you.

What if I agree to be in the research and then change my mind?
If you decide to leave the study early, we ask that you inform the principal investigators , Dale Brunelle at 701-795-8282 or dale.brunelle@usda.gov or James Roemmich at 701-795-8272 or james.roemmich@usda.gov.

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You will be informed by the research investigator[s] of this study of any significant new findings that develop during the study which may influence your willingness to continue to participate in the study.

There may be certain medical circumstances where you may be removed from the study without your prior approval. If there is deteriorating health or other conditions that might make continued participation harmful to you, we will ensure your safety is put first.

Who can answer my questions about this research?
If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page.

This research is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at 701.777.4279 or UND.irb@UND.edu if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.
- You may also visit the UND IRB website for more information about being a research subject: http://und.edu/research/resources/human-subjects/research-participants.html

Your signature documents your consent to take part in this study. You will receive a copy of this form.

Subject's Name: _____

_____ _____
Signature of Subject Date

I have discussed the above points with the subject or, where appropriate, with the subject's legally authorized representative.

_____ _____
Signature of Person Who Obtained Consent Date

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