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Fred Hutchinson Cancer Center

New Mexico State University

Consent to take part in a research study:

Cooking for Your Health in Southern New Mexico

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Important things to know about this study.

You are invited to participate in a research study. The purpose of this research is to understand how best to teach nutrition and cooking classes to increase fruit and vegetable intake. Classes will also provide knowledge on nutrition, chronic disease prevention, and cancer prevention. The study is being conducted by researchers at New Mexico State University in Las Cruces, NM and Fred Hutchinson Cancer Center in Seattle, WA.

People who agree to join the study will be asked to attend 6 in-person classes over a 6-week period (1 session per week). Before each class, participants will be asked to spend about 30 minutes watching a short video and/or trying a new cooking skill at home. Each in-person class will last a total of 90 minutes, starting with 60-minute hands-on experiential cooking sessions to practice new cooking skills in a teaching kitchen, followed by sharing a meal and discussing the information learned. After each class, participants will be asked to provide feedback in a short questionnaire. At every other class (classes 2, 4, and 6) a registered dietitian will be available virtually to answer participant questions.

We do not know if this study will benefit participants. Although the study may not benefit participants directly, we hope the information we learn will improve our knowledge about the best way to teach people how and why to increase their fruit and vegetable intake.

You do not have to join this study, and if you decide to join, you have the right to stop at any time. Changing your diet could cause side effects such as discomfort and bloating, and there can be an inconvenience with attending the in-person classes, as described below in this form.

Below is a more complete description of this study. Please read this description carefully. You can ask any questions you want to help you decide whether to join the study. If you join this study, we will give you a signed copy of this form to keep for future reference.

We are inviting you to join this research study.

We are doing a research study to understand how best to teach nutrition and cooking classes to increase fruit and vegetable intake in New Mexican communities. We want to know if these classes provide appropriate and effective information to help participants understand how and why to increase fruit and vegetable intake. Since you live in Southern New Mexico region, we are inviting you to join this study. We will enroll up to 40 people.

If you agree to be in this study, you will do the following: attend a weekly in-person cooking class with each session lasting 90 minutes for 6 weeks. Participation in the study is expected to last about 10 weeks once classes begin. If you agree to be in the study, you will do the following:

- Answer survey questions on the phone or using online questionnaires.
- Measure your fruit and vegetable intake 3 different ways: answering questions in a questionnaire about the foods you eat, measuring the amount of carotenoids (a compound found in many fruits and vegetables) and by placing your finger in a sensor.
- For 6 weeks, attend weekly in-person classes that last about 90 minutes.
- Before each in-person class, spend about 30 minutes watching a short video and/or trying a new cooking skill at home.
- After each class, answer a short set of questions.
- Once all of the classes are over, repeat survey questions on the phone or using online questionnaires, and repeat 3 types of measurements for fruit and vegetable intake.
- Once you have completed all of the data collection measures, you will be invited to participate in a focus group to discuss your experience in the classes at the end of the study.

You can decide to not participate in this study. You are free to say yes or no or to drop out any time after joining. There is no penalty if you do or do not join this study. Whatever you decide, participating in this study will not change your regular medical care.

What research tests and procedures are part of this study? What will happen in this study?

If you decide to join this study, you will do these tests and procedures:

- **Baseline Surveys** : After you sign an online consent form, you will be directed to complete online surveys in a system called “REDCap”. You will also receive a survey link via email to a Food Frequency Questionnaire (FFQ). Once the surveys are completed, we will contact you to provide further information about the class schedule, and location.

First Session of Cooking for your Health in Southern New Mexico: At your first session, you will arrive at your local County Extension office, 30 minutes earlier than normal, so study staff can check you in, answer any questions you have, and measure your height, weight and measure your fruit and vegetable intake with a veggie meter scan.

The Veggie Meter scan, is a portable non-invasive fingertip scan that measures skin carotenoid levels, meaning it measures the skin pigments that show a person's intake of fruit and vegetables that are red, yellow, or orange.

After completing the data collection, the instructor will begin the first session.

- **Cooking for your Health in Southern New Mexico Sessions:** The sessions will be led by New Mexico State University (NMSU) Cooperative Extension agents that will be in-person in English. Before each session, you will be expected to complete 15-30 minutes of "pre-work" where you will watch a video and/or practice a new cooking skill.

Each in-person session will start with a 60-minute hands-on cooking class in a teaching kitchen, followed by a 30-minute meal that will include a group discussion about information learned.

At every other class (classes 2, 4, and 6) a registered dietitian will be available either in person or by Zoom to answer participant questions.

After each session, you will provide feedback in a short questionnaire.

You will have access to the session materials on the CookforYourLife.org website. The study team will provide you with login information to access the pre-work videos, handouts, and the digital cookbook that will include recipes you will cook in class.

- **Week 8:** Study staff will conduct various follow-up assessments over the phone, in person, by virtual meeting, and in REDCap. We will repeat some of the surveys that were performed during the baseline visit, including the Veggie Meter scan.
- **Week 10:** Once all measures are completed, you will be invited to participate in a focus group held online or in person at the end of the study.

Risks of being in this study

There are some potential risks with participating in this study. These potential risks are listed below. There may be some unknown risks linked with being in this study that are not listed.

- Discomfort: there may be some discomfort in completing questionnaires. Participants can decline to complete a survey or skip questions at their own discretion.
- Loss of confidentiality: A risk of taking part in this study is the possibility of a loss of confidentiality. Loss of confidentiality includes having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. We'll try to protect your information, but we can't guarantee privacy. Their plans for keeping your information private are described in the 'confidentiality' section of this consent form.

- Gas and bloating: Recommended dietary changes may include gas and bloating due to increasing fiber consumption by eating more fruits and vegetables.
- Inconvenience: The time and frequency of the class pre-work, class sessions, and data collection may be an inconvenience to your schedule. Travel to and from the session may also be an inconvenience.
- Other risks: There may be other risks of taking part in this research study that we don't know about. If we learn about other risks, we will tell you what they are as soon as we find them so you can decide if you want to continue in the study.

What are the benefits?

We do not know if this study will directly benefit you. You may increase your understanding of nutrition and chronic disease and understand how to plan for and prepare healthy foods. Although the study may not benefit participants directly, we hope the information we learn will improve our knowledge about the best way to teach people how and why to increase their fruit and vegetable intake.

Protecting your Privacy as an Individual and the Confidentiality of Your Personal Information

Some people or organizations may need to look at your research records for quality assurance or data analysis. These include:

- Researchers involved with this study.
- The study sponsor and their agents.
- New Mexico State University and Fred Hutchinson Cancer Center.
- Institutional Review Boards (IRB), including the Fred Hutchinson Cancer Center IRB. An IRB is a group that reviews the study to protect your rights as a research participant.
- US National Institutes of Health, National Cancer Institute, Office for Human Research Protections, and other agencies as required.

We will do our best to keep your personal information confidential. But we cannot guarantee total confidentiality. Your personal information may be disclosed if required by law. For example, we are required to report certain diseases and infections to public health authorities. We are also required to report suspected abuse or neglect of children and vulnerable adults. Workplace safety rules may require health workers to contact you about lab tests. Or a court may order that study information be disclosed. Such cases are rare.

We will not use your personal information in any reports about this study, such as journal articles or presentations at scientific meetings.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

If we want to use your tissue and information for other research or share it with other scientists for research, an ethics review committee (IRB) will review the request. The IRB will decide if we need to ask for your consent to do the research.

Certificate of Confidentiality

At the start of the study, this research is covered by a Certificate of Confidentiality from the U.S. government. This Certificate generally means that we would not have to give out identifying information about you even if we were asked to by a court of law. We would use the Certificate to resist any demands for identifying information. The Certificate may not last the duration of the research. Talk to the study staff if you have questions about this.

We could not use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person.

This protection has some limits. We would voluntarily provide the information:

- To a member of the federal government who needs it in order to audit or evaluate the research.
- To the funding agency and groups involved in the research, if they need the information to make sure the research is being done correctly.
- To the federal Food and Drug Administration (FDA), if required by the FDA.
- To someone who is accused of a crime, if they believe that our research records could be used for defense.
- To authorities, if we learn of child abuse, elder abuse, or if participants might harm themselves or others.

Will you pay me to be in this study?

At the in-person classes, you will share a meal with your classmates and instructor. You will also receive some kitchen tools to take home, such as a knife, cutting board, and measuring cups.

Each time you complete a data collection timepoint, you will receive an electronic gift card to compensate you for your time and effort:

- \$25 electronic gift card after completion of the baseline data collection procedures.
- \$25 electronic gift card after completion of the follow-up data collection procedures.
- \$25 electronic gift card if you participate in the optional focus group at the end of the study.

How much will this study cost me?

There may be some extra costs for being in the study. These costs may include expenses for purchasing fruits and vegetables to try new cooking skills at home, childcare during classes, and/or transportation to and from study visits or in-person sessions.

What if I get sick or hurt after I join this study?

For a life-threatening problem, call 911 right away or seek help immediately. Contact your study doctor when the medical emergency is over or as soon as you can.

For all other medical problems or illness related to this research, immediately contact Dr. Heather Greenlee at (206) 667-4502 or Dr. Ivette Guzman at (575) 646-3405. They will refer you for treatment. You or your health insurance will have to pay for the treatment. There are no funds to pay you for a research-related injury, added medical costs, loss of a job, or other costs to you or your family. State or national law may give you rights to seek payment for some of these expenses. You do not waive any right to seek payment by signing this consent form.

You or your insurer will be billed for treatment of problems or complications that result from your condition or from standard clinical care.

Your rights

- You do not have to join this study. You are free to say yes or no.
- If you join this study, you do not have to stay in it. You may stop at any time (even before you start). There is no penalty for stopping.
- If you get sick or hurt in this study, you do not lose any of your legal rights to seek payment by signing this form.
- During the study, we may learn new information you need to know. For example, some information may affect your health or well-being. Other information may make you change your mind about being in this study. If we learn these kinds of information, we will tell you.

For more information

Please call 206-667-4502 or email cookingforyourhealth@nmsu.edu if you have questions or would like to speak to someone about this consent form.

If you have questions or concerns about this study, you can talk to Dr. Heather Greenlee or Dr. Ivette Guzman anytime. Additional people are listed below.

If you have questions about:

Call:

This study (including complaints and requests for information)

(206) 667-4502 Dr. Heather Greenlee, Multiple Principal Investigator
(575) 646-3405 Dr. Ivette Guzman, Multiple Principal Investigator
(206) 667-5625 Jenny Whitten, Project Manager

Your rights as a research participant

(206) 667-5900 or email
irodirector@fredhutch.org - Director of Institutional Review Office, Fred Hutchinson Cancer Center

During this study, we do not expect any test results that would affect your care, so we do not plan to return results to you.

What will my information be used for?

Your medical information will be used for the purposes of this study. Your information, including medical information and surveys you participate in for this study, will be used to understand how best to teach nutrition and cooking classes to increase fruit and vegetable intake.

Read each question and think about your choice. When you decide on each question, please circle **YES** or **NO**.

Is it OK if someone contacts you in the future to ask you to donate more information for research?

(circle one)

YES

NO

Initials:

Date:

Signatures

Please sign below if you:

- have read this form (or had it read to you);
- had the opportunity to ask any questions you have;
- had the opportunity to discuss the research with the person obtaining consent; and
- agree to participate in this study.

Participant (age 18+):

Printed Name

Signature

Date

Researcher's statement

I have discussed the research study, including procedures and risks, with the person signing above. A copy of the signed consent form will be given to the participant.

Person obtaining consent signature:

Printed Name

Signature

Date

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Previous consent version date: 10/15/2024

Copies to: