

# Document Coversheet

Study Title: Improving Healthy Living Opportunities: Laurel Harvest

Institution/Site:	University of Kentucky
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## Consent to Participate in a Research Study

IRB Approval  
2/14/2023  
IRB # 64602  
NMED

### KEY INFORMATION FOR PROMOTING HEALTHY EATING IN LAUREL COUNTY

We are asking you to choose whether or not to volunteer for a research study about programs promoting healthy eating in Laurel County and testing if offering these programs to the community improves access to food and intake of fruits and vegetables. Individuals who are over age 18, fluent in English, not pregnant, and have lived in Laurel or Pike County for at least 1 year with no plans of moving out of the county in the next 3 years can participate. This page gives you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

#### WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

By doing this study, we hope to learn more about the types of healthy eating programs that improve access to food and intake of fruits and vegetables in communities like yours.

Over 2 years, we will test if offering the healthy eating programs throughout the county improved access to food and intake of fruits and vegetables. Your participation in this research will include (1) a survey, (2) 24 hour dietary recall, and (3) carotenoid RS, which is a non-invasive instrument that measures fruit and vegetable intake from a finger scan (approximately 45 minutes). We will ask you to complete each of these 3 measures 1 time per year for 3 years (3 times total).

Also, we will contact you 1-2 times per year for 2 years by telephone, email, or mail (approximately 5 minutes) to give you updated information about the healthy eating programs in the county.

Pike County will be used as a comparison county for the study. Cancer screening programs will be offered in Pike County instead of healthy eating programs.

#### WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

For a complete description of risks, refer to the Detailed Consent. Your participation in this study may not directly benefit you, but by participating, your feedback will help us better understand what types of healthy eating programs are most helpful for people like you.

#### WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

We believe the benefits (providing helpful information about supporting healthy eating in your county) outweigh the risks of time and inconvenience. Other than time, another risk may include feelings of discomfort during survey questions about having enough food to eat. If you ever feel uncomfortable during the study, you are free to skip questions or stop participating at any time.

#### DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits, or rights you would normally have if you choose not to volunteer.

#### WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study contact Kathryn Cardarelli of the University of Kentucky, Department of Health, Behavior, and Society at [Kathryn.Cardarelli@uky.edu](mailto:Kathryn.Cardarelli@uky.edu) or 859-323-5357

If you have any concerns or questions about your rights as a volunteer in this research, contact staff in the University of Kentucky (UK) Office of Research Integrity (ORI) between the business hours of 8am and 5pm EST, Monday-Friday at 859-257-9428 or toll free at 1-866-400-9428.

## **DETAILED CONSENT:**

### **ARE THERE REASONS WHY YOU WOULD NOT QUALIFY FOR THIS STUDY?**

You may not participate in this study if you are under age 18, not fluent in English, pregnant, not a resident of Laurel or Pike County, have lived in the county for less than 1 year or have plans to move out of the county in the next 3 years.

### **WHERE WILL THE STUDY TAKE PLACE AND WHAT IS THE TOTAL AMOUNT OF TIME INVOLVED?**

The research study will be conducted at the County Extension Office during 1 session that will last about 45 minutes. We will ask you to come to 1 session per year for 3 years (a total of 3 times during the entire study). We will also contact you 1-2 times per year for 2 years by phone, email, or mail to give you updated information about the healthy eating programs in the county. Getting this information will take about 5 minutes per year. The total amount of time you will be asked to volunteer for this study is 2 hours and 25 minutes over the next 3 years.

### **WHAT WILL YOU BE ASKED TO DO?**

- We will ask you to complete a (1) survey, (2) 24 hour dietary recall, and (3) finger scan of fruit and vegetable intake (carotenoid RS scan) that will last about 45 minutes in total. We will ask you to complete each of these 3 measures 1 time per year for 3 years (a total of 3 in-person visits during the entire study).
- Carotenoid RS Scan (finger scan of fruit and vegetable intake) – Carotenoid RS is a non-invasive instrument that uses a technique called reflectance spectroscopy, which involves shining a light on the skin of the hand to measure carotenoids in the skin. Carotenoids are compounds found in fruits and vegetables. Measuring changes in carotenoids in the body is a way to measure changes in fruit and vegetable intake. (This is strictly an objective measure of carotenoids in the skin. It is not used for diagnosing any medical condition)
- We will ask you to complete the survey and 24 hour dietary recall on your own using an iPad. If you need help completing the survey and dietary recall for any reason, such as visual limitations, trouble reading and understanding questions, or not being comfortable using iPads, a member of the research team will read the questions to you aloud and ask you to provide your answers verbally.
- Finally, we will ask to contact you 1-2 times per year for 2 years by phone, email, or mail to give you information about the healthy eating programs in the county. Getting this information will take about 5 minutes per year.

### **WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?**

Risks may include feelings of discomfort or embarrassment from answering survey questions about having enough food to eat. Survey questions and data will be kept anonymous, but if you feel uncomfortable with a question, you are free to skip questions or stop participating at any time.

### **WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?**

We do not know if you will get any benefit from taking part in this study. However, by participating, your feedback will help us better understand what types of healthy eating programs are most helpful for people like you. Information learned may help others.

### **IF YOU DON'T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?**

If you do not want to be in the study, there are no other choices except not to take part in the study.

### **WHAT WILL IT COST YOU TO PARTICIPATE?**

There are no costs associated with taking part in this study other than the possibility of cost to travel to the Extension Office.

### **WHO WILL SEE THE INFORMATION THAT YOU GIVE?**

When we write about or share the results from the study, we will write about the combined information. We will keep your name and other identifying information private.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. Data will not contain your name or personal information. All data will be assigned a study ID.

You should know that there are some circumstances in which we may have to show your information to other people. For example, the law may require us to share your information with:

- a court or agencies, if you have a reportable disease/condition;
- authorities, such as child or adult protective services, if you report information about a child or elder being abused;
- authorities or a mental health professional if you pose a danger to yourself or someone else (e.g. suicidal thoughts).

We will use REDCap, a data collection software. It is important to note that any data collection process undertaken through the use of third-party software comes with potential risks. Included among these risks is a potential breach of confidentiality. The study team will take all available precautions to prevent this from occurring, although we cannot guarantee that your identity will never become known.

REDCap is a secure, web-based program to capture and store data at the University of Kentucky. We will make every effort to safeguard your data in REDCap. However, given the nature of online surveys, we cannot guarantee the security of data obtained by way of the Internet.

#### **CAN YOU CHOOSE TO WITHDRAW FROM THE STUDY EARLY?**

You can choose to leave the study at any time. You will not be treated differently if you decide to stop taking part in the study.

If you choose to leave the study early, data collected until that point will remain in the study database and may not be removed.

The investigators conducting the study may need to remove you from the study. This may occur for a number of reasons. You may be removed from the study if:

- you are not able to follow the directions,
- we find that your participation in the study is more risk than benefit to you, or
- the agency paying for the study chooses to stop the study early for a number of reasons.

#### **WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?**

You will receive a \$30 gift card for each session you take part in this study. With a few exceptions, study payments are considered taxable income reportable to the Internal Review Service (IRS). A form 1099 will be sent to you if your total payments for research participation are \$600 or more in a calendar year.

#### **WILL YOU BE GIVEN INDIVIDUAL RESULTS FROM THE RESEARCH TESTS/SURVEYS?**

Generally, tests/surveys done for research purposes are not meant to provide results that apply to you alone.

#### **WILL WE CONTACT YOU WITH INFORMATION ABOUT PARTICIPATING IN FUTURE STUDIES?**

The research staff would like to contact you with information about participating in this or future studies. If so, it will be limited to 1-2 times per year.

Do you give your permission for the investigator or staff to contact you regarding your willingness to participate in future research studies? <input type="checkbox"/> Yes <input type="checkbox"/> No         Initials _____
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**WHAT ELSE DO YOU NEED TO KNOW?**

If you volunteer to take part in this study, you will be 1 of about 320 people to do so.

The U.S. Department of Agriculture's National Institute of Food and Agriculture is providing financial support and/or material for this study.

**WILL YOUR INFORMATION BE USED FOR FUTURE RESEARCH?**

Your information collected for this study will NOT be used or shared for future research studies, even if we remove the identifiable information like your name, address, or email.

## INFORMED CONSENT SIGNATURES

This consent includes the following:

- Key Information Page
- Detailed Consent

You are the subject or are authorized to act on behalf of the subject. You will receive a copy of this consent form after it has been signed.

_____ <b>Signature of research subject or, if applicable, parent or guardian</b>	_____ <b>Date</b>
_____ <b>Printed name of research subject or, if applicable, parent or guardian</b>	
_____ Printed name of [authorized] person obtaining informed consent	_____ Date