IRB Approval
7/31/2018
IRB # 44215
ID # 47220



**KEY INFORMATION FOR FRESH STEPS**

You are being invited to take part in a research study about the health impacts of eating more fruits and vegetables and walking approximately 1 mile per week.

## WHAT IS THE PURPOSE, PROCEDURES, AND DURATION OF THIS STUDY?

By doing this study, we hope to learn if receiving $10 to spend on fruits and vegetables at the Farmer's Market from June-September and receiving a $20 healthy prepared meal October-January, in combination with walking approximately 1 mile per week improves your health. You will be asked to participate in health screenings in May, September, and February. You will also be given a pedometer and asked to wear it throughout the course of the study. Your participation in this research will last about 10 months.

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

You may want to volunteer for this study as you will receive $10 per week (June-September) to spend on fruits and vegetables at the Farmer's Market, and a prepared $20 meal per week (October-January) from CANES Kitchen. You will also have access to the Cowan Community Center for free once per week.

For a complete description of benefits, refer to the Detailed Consent.

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

You may not want to volunteer for this study if you are unable to commit to participating for 10 months, are under 18 years old, pregnant, or unable to walk 1 mile, once per week. For a complete description of risks, refer to the Detailed Consent/Appendix.

## 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?

The person in charge of this study is Dawn Brewer, PhD, RD, LD of the University of Kentucky, Department of Dietetics and Human Nutrition. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: 859-257-1661 (office); dawn.brewer@uky.edu; 209C Funkhouser Building University of Kentucky Lexington, Kentucky 40506

If you have any questions, suggestions or concerns 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 should not participate if: you are less than 18 years old, are unable to walk at least 1 mile at a time, or pregnant.

## WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?

The research procedures will be conducted at the Letcher County Extension Office. You will need to come 3 times during the study. Each of those visits will take about 30 minutes. The total amount of time you will be asked to volunteer for this study is 1.5 hours, plus however long you decide to stay at the Farmer's Market or CANES kitchen over the next 10 months.

## WHAT WILL YOU BE ASKED TO DO?

All participants will fill out a survey and have their weight, height, waist circumference, blood pressure, carotenoid status, and finger stick cholesterol and A1c taken three times – once in May 2018, the second time in September 2018, and the third time in February 2019.

In June through September, all participants will be asked to sign in and report the number of steps taken over the past week at the parking lot near the swimming pool to receive their voucher. All participants will turn in their voucher to the market manager, who will rip off the small end in return for $10 worth of tokens to spend on fruits and vegetables at the farmer's market. The part of the voucher returned to you will ask you to do two things. First, you will be asked to write down what fruits and vegetables you bought at the market that day. Second, you will be asked how you used the fruits and vegetables you purchased the previous week. This voucher must be turned in to the market manager as you leave the market in order for you to receive your voucher the following week.

In October through February, all participants will be asked to walk 1 mile at the Cowan Community Center, and track this 1 mile using your assigned pedometer. Once per week, you will be asked to pick up a prepared meal at CANES Kitchen and turn in how many steps you walked over the past week.

## WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

To the best of our knowledge, the things you will be doing have no more risk of harm than you would experience in everyday life. The risks associated with finger stick readings are minimal and short term, but may include initial pain and tenderness. No participant will be stuck more than three times and all participants will receive band aids and proper attention and care. There are no risks associated with the use of a carotenoid scanner. Additionally, there is always the risk for unforeseeable risks.

## 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, some people have experienced improved self-perceived health, a decrease in blood pressure, waist circumference, cholesterol, and a1cwhen they eat more fruits and vegetables and increase their physical activity. However, if you take part in this study, information learned may help others with your condition.

## WHAT WILL IT COST YOU TO PARTICIPATE?

There are no costs associated with taking part in the study.

## 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. The combined

information will only reveal summarized data without identifiable information. The de-identified data will be available electronically and stored on a password protected computer. The electronic document containing names with respective survey codes will be deleted after post-survey data has been collected and therefore will not be stored. The list will be deleted by January 2020. Any study materials and raw data will be retained for 6 years after study closure in a locked drawer within a locked office or on a password protected computer. The primary investigator and program manager assigned to the project and involved in data collection will have access to these items. Officials from the University of Kentucky or the National Institute of Health may look at or copy pertinent portions of records that identify you.

**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 wish to withdraw from the study you can send a written letter to Dawn Brewer at 209C Funkhouser Building University of Kentucky Lexington, Kentucky 40506.

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. The study intervention, will no longer be provided to you. This may occur for a number of reasons. You may be removed from the study if:

- you are not able to follow the directions,
- they 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 scientific reasons.

**ARE YOU PARTICIPATING, OR CAN YOU PARTICIPATE, IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?**

You may take part in this study if you are currently involved in another research study. It is important to let the investigator/your doctor know if you are in another research study. You should discuss this with the investigator/your doctor before you agree to participate in another research study while you are in this study.

**WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?**

If you believe you are hurt or if you get sick because of something that is due to the study, you should call Dawn Brewer at 859-257-1661 immediately.

It is important for you to understand that the University of Kentucky does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, the University of Kentucky will not pay for any wages you may lose if you are harmed by this study.

Medical costs related to your care and treatment because of study-related harm

- will be your responsibility; **or**
- may be paid by your insurer if you are insured by a health insurance company (you should ask your insurer if you have any questions regarding your insurer's willingness to pay under these circumstances); **or**
- may be paid by Medicare or Medicaid if you are covered by Medicare or Medicaid (If you have any questions regarding Medicare/Medicaid coverage you should contact Medicare by calling 1-800-Medicare (1-800-633-4227) or Medicaid 1-800-635-2570.).

A co-payment/deductible may be needed by your insurer or Medicare/Medicaid even if your insurer or Medicare/Medicaid has agreed to pay the costs). The amount of this co-payment/deductible may be costly.

You do not give up your legal rights by signing this form.

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

All participants will receive a farmer's market t-shirt for their participation in May, a $10 gift card for their participation in September, a $10 farmers market voucher for every Saturday that they sign in at their designated place, and a prepared meal valued at $20 once per week from CANES Kitchen after walking 1 mile at least once during the week.

**WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?**

You will be informed if the investigators learn new information that could change your mind about staying in the study. You may be asked to sign a new informed consent form if the information is provided to you after you have joined the study.

**WHAT ELSE DO YOU NEED TO KNOW?**

If you volunteer to take part in this study, you will be one of about 75 people to do so.

The National Institute of Health (NIH) is providing financial support and/or material for this study.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

# INFORMED CONSENT SIGNATURE PAGE

**You are a participant. This consent includes the following:**

- **Key Information Page**
- **Detailed Consent**

**You will receive a copy of this consent form after it has been signed.**

_____ _____
**Signature of research subject** **Date**

_____
**Printed name of research subject**

_____ _____
Printed name of [authorized] person obtaining informed consent Date

_____
Signature of Principal Investigator or Sub/Co-Investigator