RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

STUDY TITLE: Richmond Health and Wellness Program (RHWP) Prescription Produce Plan (PPP) Pilot Study
VCU INVESTIGATOR: Kimberly Battle, PhD, VCU SON, (804)828-0521
SPONSOR: VCU School of Nursing, Clinical Sponsors Program

ABOUT THIS CONSENT FORM

You are being invited to participate in a research study. **It is important that you carefully think about whether being in this study is right for you and your situation.**

This consent form is meant to assist you in thinking about whether or not you want to be in this study. **Please ask the investigator or the study staff to explain any information in this consent document that is not clear to you.** You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

Your participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled, and you may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.

AN OVERVIEW OF THE STUDY AND KEY INFORMATION

Why is this study being done?
You are invited to participate in a research study focused on examining how a Prescription Produce Plan (PPP) may influence vegetable consumption, self-management [self-efficacy], resilience, and quality of life in older adults. This research study involves meeting with a team of VCU students and faculty to learn information about nutrition.

The purpose of this research study is to find out if access to fresh produce along with individual goal setting and education influences vegetable consumption, self-management [self-efficacy], resilience, or quality of life. We think access to fresh produce along with individual goal setting and education, may improve all of the above. This study will allow us to learn more about it.

We will ask you to record your blood pressure readings, weight, number of vegetables consumed, and blood glucose readings (if you already do this) in a notebook that we provide you at the first study visit and report this information to us during future study visits.

The intervention for this study centers on the students and faculty giving you individualized teaching around goals that are tracked. All the procedures in this study are experimental.

What will happen if I participate?

In this study, you will be asked to do the following things:

1. You will be asked to complete a total of five (5) surveys and the consent process during the enrollment visit lasting approximately 30 to 60 minutes.
2. During the initial study visit (#1), we will provide you with an automatic blood pressure machine, demonstrate how to use it with you, and give you a handout with instructions on how to record and monitor your blood pressure at home. You are asked to record your blood pressure readings and blood glucose readings [if you already do this] once a week in a notebook that we give you and then self-report the blood pressure and blood glucose readings at the next two (2) study visits.
3. Additionally, you will receive individualized teaching supporting obtaining the goals at this visit and future study visits. The study team will discuss with you the contents of the produce bags and how to cook the contents of the bag. We will also work with you to set goals for yourself. Goals for this study will focus on vegetable consumption, weight management, and either blood pressure and/or blood glucose measurements. The initial study visit may last approximately 30 minutes.
4. At the end of the initial study visit, you will receive a voucher from the Shalom Farms Mobile Market for once a week redemption over the course of 6 weeks while participating in the program. VCU Health Hub 25th Street participants will receive a produce bag at the end of this visit and will need to come to the Health Hub weekly to pick up the produce bag.
5. Subsequent study visits will focus on your goals. You will meet with us to discuss if goals were met or not met and we will provide individualized teaching to support meeting your set goals. The study team will discuss with you the contents of the produce bags and how to cook the contents of the bag as well as how to read frozen and/or canned food labels. We will ask you to meet with us twice after the initial study visit for approximately 20 to 30 minutes at each visit. You will meet at Week #3 and at Week #6.
6. You will record in provided notebooks your blood pressure, weight, and blood glucose [if you are already checking your blood glucose prior to participating in this study]. These measurements will also be reported during study visits.
7. You are asked to meet with a member of the research team after six (6) weeks of participating in the study to complete a total of three (3) post-study surveys. This visit will last approximately 30 minutes.

Your participation in this study will last up to 8 weeks for a total of approximately 3 hours of in person visits. Approximately 30 individuals will participate in this study.

What are the risks and benefits of participating?

There are both risks and benefits of participating in research studies.

Risks and Discomforts	Benefits to You and Others
• Participation in research might involve some loss of privacy. There is a small risk that someone outside the research study could see and misuse information about you. • The study questionnaires ask questions that are sensitive or personal in nature and may make you feel uncomfortable.	This is not a treatment study, and you are not expected to receive any direct medical benefits from your participation in the study. The information from this research study may lead to better access to fresh produce for older adults with or without medical conditions.

Now that you have a general overview of the study, we want to provide the details about what your participation involves. Please read, or have someone read to you, the rest of this document. If there is anything you do not understand, be sure to ask the study staff.

Alternatives

If you do not want to take part in the study but would like to receive some help receiving vegetables or fruit, please contact the study team to discuss if there are any programs or resources to receive help. You may also contact the Feed More Hunger Hotline at (804)521-2500, ext. 631 between 9am to 4pm, Monday to Friday.

We are not able to customize the weekly produce bags to meet specific requests. However, we do encourage you to trade or give away any produce that you do not like, do not want to eat, or are unable to eat for any reason.
If you choose not to participate in this study, you may still participate in the RHWP program.

WHAT WILL HAPPEN IF I PARTICIPATE IN THE STUDY?

After responding to three questions to see if you are eligible for the study, you are scheduled for an enrollment visit to complete the study consent form, fill out questionnaires about Social Determinants of Health, Food Insecurity, Self-Efficacy, Resilience, and Quality of Life as well as a Demographic Information Sheet. You will self-report your weight, height, and number of vegetable servings eaten per day at this time as well.

During study visits, you will receive health and nutrition education and support with goal setting. Future study visits are scheduled at the end of the previous visit. At each visit, you will be asked to self-report your blood pressure, weight, blood glucose (if applicable) and number of vegetable servings consumed each day.

The last visit will include another interview with the study staff, and you will be asked about your overall experience during the study completing three (3) surveys about quality of life, self-efficacy, and resilience. We will give you a coupon to be redeemed with the Shalom Farms Mobile Market to assist you with maintaining vegetable consumption since your participation in the study has ended.

WHAT ARE THE COSTS?

The sponsor is paying for everything in this study. You will not be charged for any study visits, tests, or procedures.

WILL I BE PAID TO PARTICIPATE IN THE STUDY?

Each week while participating in this study, you will receive one (1) ten to twenty-pound prepackaged produce bag from Shalom Farms Market by redeeming a voucher or coming to pick up the produce bag. Completing this study entitles you to a total of six (6) produce bags. If you withdraw before the end of the study, you can continue to use the voucher. After the final meeting, we will help you by providing you with coupons to assist with purchasing fresh vegetables from Shalom Farms. These coupons are worth a total of $15 to $20 and all participants will receive the same amount.

CAN I STOP BEING IN THE STUDY?

You can stop being in this research study at any time. Leaving the study will not affect your relationship with RHWP, employment status, or academic standing at VCU or VCU Health. Tell the study staff if you are thinking about stopping or decide to stop.

If you leave the study before the final regularly scheduled visit, we ask that you notify us at (804)828-0521. Stopping participating in the study early may not result in harm.

Your participation in this study may be stopped at any time by the investigator without your consent. The reasons might include:

- the investigator thinks it necessary for your health or safety
- the sponsor has stopped the study
- you have not followed study instructions
- administrative reasons require your withdrawal

HOW WILL INFORMATION ABOUT ME BE PROTECTED?

VCU and the VCU Health System have established secure research databases and computer systems to store information and to help with monitoring and oversight of research. Your

information may be kept in these databases but are only accessible to individuals working on this study or authorized individuals who have access for specific research related tasks. Identifiable information in these databases are not released outside VCU unless stated in this consent or required by law. Although results of this research may be presented at meetings or in publications, identifiable personal information about participants will not be disclosed.

Personal information about you might be shared with or copied by authorized representatives from the following organizations for the purposes of managing, monitoring and overseeing this study:

- The study Sponsor, representatives of the sponsor and other collaborating organizations
- Representatives of VCU and the VCU Health System

In general, we will not give you any individual results from the study. If we find something of medical importance to you, we will inform you although we expect that this will be a very rare occurrence.

In the future, identifiers might be removed from the information and samples you provide in this study, and after that removal, the information/samples could be used for other research studies by this study team or another researcher without asking you for additional consent.

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 Website will include a summary of the results. You can search this Web site at any time.

WHOM SHOULD I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY?

The investigator and study staff named below are the best person(s) to contact if you have any questions, complaints, or concerns about your participation in this research:

Kimberly Battle, battlekd@vcu.edu, (804)828-0521

If you have general questions about your rights as a participant in this or any other research, or if you wish to discuss problems, concerns or questions, to obtain information, or to offer input about research, you may contact:

Virginia Commonwealth University Office of Research
800 East Leigh Street, Suite 3000, Box 980568, Richmond, VA 23298
(804) 827-2157; https://research.vcu.edu/human-research/

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions**.**

STATEMENT OF CONSENT

I have been provided with an opportunity to read this consent form carefully. All of the questions that I wish to raise concerning this study have been answered. By signing this consent form, I have not waived any of the legal rights or benefits to which I otherwise would be entitled. My signature indicates that I freely consent to participate in this research study. I will receive a copy of the consent form for my records.

_____	
Adult Participant Name (Printed)	
_____	_____
Adult Participant's Signature	Date
_____	
Name of Person Conducting Consent Discussion (Printed)	
_____	_____
Signature of Person Conducting Consent Discussion	Date
_____	_____
Principal Investigator Signature (if different from above)	Date