Informed Consent to Participate in Research
Information to consider before taking part in research that has no more than minimal risk.

Title of Research Study: Examining Validity and Sensitivity of Pressure-Mediated Reflection Spectroscopy as a Measure of Fruit and Vegetable Consumption in a Diverse Community Sample

Sponsor/Funding Source: NIH/NHLBI
Sponsor Protocol #: ECU IRB# UMCIRB 17-001242
Principal Investigator: Stephanie Pitts (Person in Charge of this Study)
Institution, Department or Division: East Carolina University Department of Public Health
Address: 115 Heart Drive, MS 660, Room 2239
Telephone #: (252) 744-5572

Researchers at East Carolina University (ECU), the University of Minnesota (UMN) and Baylor College of Medicine (BCM) study issues related to society, health problems, environmental problems, behavior problems and the human condition. To do this, we need the help of volunteers who are willing to take part in research.

The purpose of this research study is to confirm that the Veggie Meter® device is measuring carotenoids, or the colorful substances found in fruits and vegetables, accurately, as well as how the Veggie Meter® measurement is related to the amount of vegetables and fruits people eat. If eligible, your participation in the study will include three 60- to 90-minute visits at the research clinic. At the first clinic visit, we will obtain a measured height and weight. If your BMI is between 18.5 and 34.9 kg/m^2, and if your fingernails are an acceptable length to allow your finger to fit in the device, we will complete the study measures for the first clinic visit. If, at this first clinic visit we find that you are ineligible, we will provide you a $10 gift card for your time. If at a subsequent clinic visit we find you are ineligible, we will provide you a $30 gift card for your time.

Why am I being invited to take part in this research?
You are being invited to take part in this research because you: 1) self-identified as one of the racial/ethnic groups of focus, 2) read and speak English, 3) have an estimated BMI between 18.5-34.9 kg/m^2, 4) are between 18 and 65 years of age, 5) are healthy with no chronic disease as determined by the health history questionnaire, 6) are not taking lipid-altering medication (medicines that lower your cholesterol or triglycerides), 7) are non-pregnant and non-lactating (and are not planning to become pregnant in the next 2 months), 8) are not allergic or intolerant to vegetables and fruits, 9) are not taking a carotenoid-containing supplement that contains > 2mg carotenoids, and 10) are weight stable (meaning you have not gained or lost more than 15 pounds in the last 3 months). By doing this research, we hope to learn whether the Veggie Meter® is an accurate assessment of the carotenoid-containing foods you consume. If you volunteer to take part in this research, you will be one of about 156 people to do so.

Are there reasons I should not take part in this research?
I understand I should not volunteer for this study if I am under 18 years of age or over 65 years of age, do not have a BMI between 18.5 and 34.9 kg/m^2, am pregnant or lactating (or have been pregnant in the last 6 weeks or am planning to become pregnant in the next 2 months), am allergic or intolerant to fruits or vegetables, am taking a carotenoid-containing supplement that contains > 2mg carotenoids, have high blood sugar, have a medical condition such as diabetes or heart disease, am taking medication that lowers cholesterol or triglycerides or if I have been diagnosed with

or treated for Crohn's disease, heart disease, chronic kidney disease, cancer other than non-melanoma skin cancer (within the last 5 years) or have other weight-related chronic diseases. Finally, I understand that I should not take part in this research if I am not willing to drink the required amount of juice every day for the 6-week study.

What other choices do I have if I do not take part in this research?

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You can choose not to participate.

Where is the research going to take place and how long will it last?
The research will be conducted at the following sites: the East Carolina University (ECU) Department of Public Health and the East Carolina Diabetes and Obesity Institute, the University of Minnesota Epidemiology Clinical Research Center (ECRC), at the USDA/ARS Children's Nutrition Research Center's Metabolic Research Unit at Baylor College of Medicine, and the Pathology Lab at Texas Children's Hospital. (At Baylor College of Medicine, if phlebotomy cannot be done in the Children's Nutrition Research Center, participants may go to a phlebotomy lab at Texas Children's Hospital for to have their blood drawn during their research visits.) You will need to come to the research clinic three times for approximately 60-90 minutes for each of the three visits during this study.

You will also be asked to do the following at each of the three clinic visits:

- Fast for 10 hours before coming to your visit. We will verify your BMI and that you will be able to complete the scan using your index finger (i.e., ensuring your fingernails are not too long to fit into the Veggie Meter®.)
- Have your blood drawn by a trained phlebotomist so we can assess the carotenoids in your blood and compare those with the carotenoids in your skin and your self-reported diet.
- Have your weight, height, and body fat percentage measured.
- Have your skin carotenoids measured using the Veggie Meter ® and your skin color/melanin index measured using a skin spectrophotometer. This involves surface coloration scans of your finger and your foream.
- Complete a questionnaire telling us about you (your age, education, race, etc.)
- Complete a Diet History Questionnaire so we can understand what you usually eat and drink. This will be completed at the clinic during your first visit and at home prior to both your second and third visits.

The second and third study visits will occur 3 weeks and 6 weeks after this first visit, respectively. We will draw a small amount of blood at each of the three visits to assess the carotenoids in your blood. There may not be any personal benefit to you, but the information gained by doing this research may help others in the future.

In addition to the three clinic visits, we will randomly assign you to one of three groups: 1) juice with no carotenoids, 2) juice with moderate amounts of carotenoids, or 3) juice with high amounts of carotenoids. You will be asked to drink juice every day for the duration of the 6-week study, and you will be given the appropriate juice to drink each day. A research assistant from your study site will call or text you to remind you to drink the juice every week. You'll need to record your juice intake and let us know if you have any problems with being able to consume the juice.

We will schedule your second visit three weeks later. The second visit will be just like the first, and you will be given 3 more weeks of juice. You will then schedule your last visit for three weeks later. This last visit will be just like the first two visits.

We will use data from the diet history questionnaire regarding the nutrients in the foods you report eating. We will send your blood to Eurofins Craft Technologies in North Carolina where trained chemists will analyze the amounts of carotenoids, glucose, and cholesterol in your blood. We will also send your blood to Baylor College of Medicine in order to conduct genetic analyses to determine your genetic ancestry and how variations in DNA can impact skin and blood carotenoid concentrations. We will not provide you with the genetic results since they are research grade

only. Finally, a portion of your blood will be sent to/stored at ECU for use in future research studies. This is different from the primary aim of the study and is described below.

<u>Banking Information and/or Samples</u>
Storing information/samples so researchers can use it in the future is called "banking." Researchers also bank information/samples so they can share it with other researchers. You have the option of doing this part of the study or deciding not to do this part of the study. For this study, samples will be stored at ECU, UMN, and BCOM in secure facilities. All samples will be stored with the participant's unique Study ID.

- We will protect your privacy and keep your information safe by:

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- Using a unique number code to label your samples and other information.
- Keeping your number code separate from name and address, social information, and other personal health information.
- Keeping your test results and other information in a computer database that is protected by advanced data protection security measures.
- Storing biological samples and other information in a secure facility at ECU, UMN, and BCOM. Access to these facilities will be restricted and monitored to make sure your samples are safe.

We will continue to review and improve the ways we keep your information private.

- We may also share your de-identified samples with any outside laboratories who may be performing laboratory analysis for researchers involved in this project.
- Your information/samples would be used for open-ended research use on any topic.
- ECU will bank the coded samples indefinitely.
- We would not be able to give you the results from research that is done using your information/samples, though we will be able to share a summary of the information we collect from all participants in this study (in aggregate).
- Your information/samples could be used to make new products, tests or findings. These may have value and may be developed and owned by the research team and/or others. If this happens, there are no plans to pay you.

What if I change my mind about banking my information/samples?

You can always tell us to stop storing your information/samples. We would destroy your information/samples and any information that identifies you. However, we would not be able to destroy or get data if we have already destroyed the link between your identifying information and your information/samples.

Your permission for the use or sharing of your information will not expire, but you may cancel it at any time. You can do this by notifying the study team in writing. If you cancel your permission, no new information about you will be collected or shared, but information that has already been provided to other researchers cannot be retrieved.

If you agree that your samples can be banked, please initial the "YES" below. If you do not want your samples to be banked, please initial the "NO".

YES: _____ NO: _____

How does the genetic analysis work?

1. Your blood sample will be stored under your name or a code linked to your name. Your identity will be protected as much as possible. Your records might be reviewed by government officials, the East Carolina University & Medical Center IRB (UMCIRB) members or support staff, or by corporate research sponsors. The University works with many

   other organizations, and information is sometimes shared among them. However, no information shared with other investigators will include your name or other identifier.

2. In addition to your name, other information about you might be connected to your blood sample. The purpose of this genetic analysis is to determine your genetic ancestry and the relationship between genetic variation and skin and blood carotenoid concentrations. No other information pertaining to gene variations related to particular diseases is going to be determined for the current study. Other information about your race, ethnic group, gender, diet, blood and skin carotenoids, or even your medical history, might be available to investigators studying your genetics. Such information might be important for research or public health. It is possible that genetic information might come to be associated with your racial or ethnic group.

What might I experience if I take part in the research?

One risk associated with this research is potential for breach in confidentiality but risk is low because electronic data are stored on restricted access servers maintained by the research institutions and physical data and samples are stored in restricted access research facilities. Any risks that may occur with this research are no more than what you would experience in everyday life. We will

draw a small amount of blood (6 milliliters, which is a little bit more than 1 teaspoon) to assess the carotenoids in your blood. The risks of blood draws are small and as a rule are limited to local bruising or swelling. Problems may include slight pain and dizziness. You may feel faint or may faint during or right after a blood draw. This causes no long-term harm. Some people with sudden changes in their food intake (such as introducing fruit) may experience digestive symptoms such as gas, bloating, abdominal pain, or diarrhea. If you experience any symptoms, you may choose to stop the study. We don't know if you will benefit from taking part in this study. There may not be any personal benefit to you but the information gained by doing this research may help others in the future.

A Federal law called the Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination based on an already-diagnosed genetic condition or disease.

Will I be paid for taking part in this research?
You will be compensated $300 across the 6-week study: $50 at the first visit, $100 after 3-week measures (midpoint), and $150 upon completion of the final measures at 6-weeks, as a Clincard (like a debit card with the money loaded onto it). If you are given a Clincard, we will have to collect your social security number.

Will it cost me to take part in this research?
There will be no cost to you for any of the study activities or procedures.

Will there be any cost to you for storage of the specimens or the genetic testing?
There will be no cost to you for the storage and use of the specimens for research purposes.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Who will know that I took part in this research and learn personal information about me?
East Carolina University, the University of Minnesota, Baylor College of Medicine, Texas Children's Hospital, and the people and organizations listed below may know that you took part in this research and may see information about you that is normally kept private. With your permission, these people may use your private information to do this research:

- The sponsors of this study.
- Any agency of the federal, state, or local government that regulates human research. This includes the Department of Health and Human Services (DHHS) and the Office for Human Research Protections.
- The University & Medical Center Institutional Review Board (UMCIRB) and its staff have responsibility for overseeing your welfare during this research and may need to see research records that identify you.
- The University of Minnesota and representatives of this institution and its affiliates, including those that have responsibilities for monitoring or ensuring compliance, such as the Quality Assurance Program of the Human Research Protection Program.

How will you keep the information you collect about me secure? How long will you keep it?
We will keep paper copies of records for a minimum of six years in locked filing cabinets, and in locked offices at ECU and in locked study files at UMN and BCM. After this time, we will shred the data. We will keep electronic copies on password protected computers for a minimum of six years. It is possible that information will be stripped of identifiers and used in future research without anyone knowing it is information from you.

What if I decide I don't want to continue in this research?
You can stop at any time after it has already started. There will be no consequences if you stop and you will not be criticized. You will not lose any benefits that you normally receive.

Will researchers seek approval from you to do future studies involving the specimens?
By signing this consent form, you are giving your permission for researchers to use your specimens as described above. Current and future research is overseen by a committee called the Institutional Review Board (IRB). The role of the IRB is to protect the rights and welfare of research participants. If other researchers want to use this data in the future, they will need to officially request it from ECU and have all IRB approvals in place. We will only provide de-identified information to other researchers.

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Who should I contact if I have questions?
The people conducting this study will be able to answer any questions concerning this research, now or in the future. At ECU, you may contact the Principal Investigator, Dr. Stephanie Pitts, at 252-744-5572, M-F, between 9 am and 5 pm.
If you have questions about your rights as someone taking part in research, you may call the University & Medical Center Institutional Review Board (UMCIRB) at phone number 252- 744-2914 (days, 8:00 am-5:00 pm).

Is there anything else I should know?
Most people outside the research team will not see your name on your research record. This includes people who try to get your information using a court order. Identifiers might be removed from the identifiable private information or identifiable biospecimens and, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your Legally Authorized Representative (LAR). However, there still may be a chance that someone could figure out the information is about you. The following research results will be provided to you at the conclusion of the study: your height, weight, body fat percentage, glucose, and cholesterol.

Will I receive anything for the use of my private identifiable information or identifiable biospecimens?
If the research conducted on your private identifiable information or identifiable biospecimens leads to a commercially valuable product, you will not be eligible for any of the profits either because it will be impossible to identify the information or biospecimen that led to the product or because you are transferring ownership of that sample.

Will my identifiable biospecimen be used for whole genome sequencing?
Whole genome sequencing is the process of determining the complete DNA sequence of an individual at a single time. However, further analysis must usually be performed to provide any biological or medical meaning of this sequence. For this research, whole genome sequencing will not occur. Genome-wide SNP genotyping (i.e. microarray analysis) will occur. This means we will look for specific variations in the genetic code for 40 pre-specified carotenoid and lipid (fat) metabolizing enzymes.

HIPAA Authorization
The purpose of the information to be gathered for this research study is to better understand whether the Veggie Meter® device is measuring carotenoids, or the colorful substances found in fruits and vegetables, accurately, as well as how the Veggie Meter® measurement is related to the amount of vegetables and fruits people eat. When taking part in research, protected health information (PHI) is collected, used, and shared with others who are involved in the research. Federal laws require that researchers and health care providers protect your PHI. Also, federal laws require that we get your permission to use collected PHI for the research. This permission is called authorization.

The individuals who will use or disclose your identifiable health information for research purposes include members of our project team at all sites (East Carolina University, University of Minnesota, Baylor College of Medicine), and members of Texas Children's Hospital involved in ordering and collecting a blood sample. Individuals who will receive your identifiable health information for research purposes include members of our project team at East Carolina University, University of Minnesota, and Baylor College of Medicine, the sponsor or other funding source to provide oversight for entire research project, the UMCIRB to provide continuing review of the research project and Institutional officials in connection with duties for monitoring research activity. The type of information accessed for this research study includes demographic information, weight, height, body fat percentage, body mass index, plasma carotenoids, cholesterol, glucose, health behaviors, and blood samples for genetic ancestry analyses. The information will be used and disclosed in such a way as to protect your identity as much as possible; however, confidentiality cannot be absolutely guaranteed. Someone receiving information collected under this Authorization could potentially re-disclose it, and therefore it would no longer be protected under the HIPAA privacy rules (federal rules that govern the use and disclosure of your health information). There is not an expiration date for this Authorization. Please note that the research does not involve treatment. Baylor College of Medicine, Texas Children's Hospital, East Carolina University, and University of Minnesota may not condition (withhold or refuse) treating you on whether you sign this Authorization.

You may not participate in this study if you do not sign this Authorization form. You may revoke (withdraw) this Authorization by submitting a request in writing to Stephanie Pitts. However, the research team will be able to use any and all of the information collected prior to your request to withdraw your Authorization. You will not be able to see your PHI in your medical record related

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to this study until the study is complete. If it is necessary for your care, your PHI will be provided to you or your physician. To authorize the use and disclosure of your health information for this study in the way that has been described in this form, please sign below and date when you signed this form. A signed copy of this Authorization will be given to you for your records.

If you have questions about the sharing of PHI related to this research study, please contact Stephanie Pitts at 252-744-5572, jilcotts@ecu.edu. Members of the University and Medical Center Institutional Review Board (UMCIRB) can also answer your questions and concerns about your rights as a research subject. The UMCIRB office number is 252-744-2914. In addition, if you have concerns about confidentiality and privacy rights, you may phone the Privacy Officer at East Carolina University at 252-744-5200**.**

I have decided I want to take part in this research. What should I do now?

The person obtaining informed consent will ask you to read the following and if you agree, you should sign this form:

- I have read (or had read to me) all of the above information.
- I have had an opportunity to ask questions about things in this research I did not understand and have received satisfactory answers.
- I know that I can stop taking part in this study at any time.
- By signing this informed consent form, I am not giving up any of my rights.
- I have been given a copy of this consent document, and it is mine to keep.

_____	_____	_____
Participant's Name (PRINT)	**Signature**	**Date**

Statement of Person Obtaining Informed Consent and Research Authorization

I have carefully explained to the person taking part in the study what he or she can expect.

I hereby certify that when this person signs this form, to the best of my knowledge, he or she understands:

- Why we are asking for blood.
- How long the sample will be used or stored.
- What will happen to the sample at the end of the time the sample is to be used or stored.
- What the potential benefits might be.
- What the known risks might be.
- How the information collected about the person will be used.
- Who will be given access to the sample.

I also certify that he or she does not have any problems that could make it hard to understand what it means to take part in this research. This person speaks the language that was used to explain this research.
This person reads well enough to understand this form or, if not, this person is able to hear and understand when the form is read to him or her.

This person does not have a medical/psychological problem that would compromise comprehension and therefore makes it hard to understand what is being explained and can, therefore, give informed consent. This person is not under any type of anesthesia or analgesic that may cloud their judgment or make it hard to understand what is being explained and, therefore, can be considered competent to give informed consent.

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_____	_____	_____
Staff Name (PRINT)	**Signature**	**Date**

Consent to Collect, Use and Disclose Social Security Numbers

IRB Study Number: UMCIRB 17-001242

Sponsor: NHLBI

Principal Investigator: Stephanie Pitts

Payments $100.00 or more for tax reporting obligations:
You are not required to provide your Social Security Number to participate in this study. However, to receive a study participation payment totaling $100.00 or more for this study, you will need to provide your Social Security Number to the University so that the University and you comply with tax reporting laws. If you are/have received payment from participating in other studies, you also will need to provide your Social Security Number. If you do not provide your Social Security Number, we cannot provide you a study participation payment totaling $600 or more in a calendar year. However, you may still choose to participate in this study by checking the second circle below. For minors (less than the age of 18), the parent or guardian's social security number will be requested.

Please check the box signifying which payment methodology you are utilizing (required):

☐ ***Greenphire debit ClinCard:***
The research coordinator will ask you to verbally give your Social Security Number to be typed directly and into the secure Greenphire system. No written record will be maintained for this personal data. The personal data you provide is stored in a secure electronic database that has access limited to only those who need to know your information. Greenphire employs reasonable precautions to prevent your personal data from loss, misuse, unauthorized access, disclosure, alteration or destruction.

☐ ***Studies not utilizing the Greenphire debit ClinCard:***
My research coordinator/nurse will provide me with a copy of the Vendor Information Form and help me complete the form. The coordinator/nurse will then return the completed form on my behalf. I understand that means the research coordinator will know my personal information, including my Social Security Number.

○ I am willing to provide my Social Security Number so that I can be paid for participation in this study. It is federal law that payments totaling $600 or more in a calendar year must be reported to the IRS for tax purposes.

○ I choose not to provide my Social Security Number. I understand that I will not be able to receive a study participation payment totaling $600.00 or more within a calendar year unless I provide my Social Security Number.

Foreign Nationals: Payments to Foreign Nationals for their participation in research studies conducted in the United States may be subject to backup withholding pursuant to Internal Revenue Code Section 1441(a). The University must determine, on a case by case basis, if backup withholding is required on remunerations paid to Foreign National participants. The University may be required to withhold tax from the gross amount due to the Foreign National at the applicable rate (potentially up to 30%) as determined by the International Tax Office. Research coordinators, please contact Accounts Payable office at participant_payments@ecu.edu to determine the methodology of payment and possible withholdings.

Reference: US Code Title 26; Subtitle F; Chapter 61; Subchapter B; Section 6109 &; N.C. Gen Stat. 132-1.10 Social Security Number and other Personal Identifying Information; N.C. Gen Stat. 143-64.60 State Privacy Act.

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Printed Name _____

Signature _____ Date_____