Tanglewood Trail Walking Program in Rural Kentucky 2020

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Consent to Participate in a Research Study

KEY INFORMATION FOR TANGLEWOOD TO TABLE

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-August, in combination with walking approximately 1 mile per week improves your health. You will be asked to participate in health screenings in May and September. Your participation in this research will last about 5 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-August) to spend on fruits and vegetables at the Farmer's Market.

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 5 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 CANE Community Kitchen. You will need to come 2 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 over the next 5 months.

WHAT WILL YOU BE ASKED TO DO?

All participants will fill out a survey and have their weight, height, waist circumference, blood pressure, and carotenoid status taken two times – once in May 2020, the second time in September 2020.

In June through September, all participants will be asked to sign in 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 ate over the last week. 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.

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. 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, and waist circumference when 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 2023. 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.

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 $10 farmers market voucher for every Thursday or Saturday that they sign in at the market (June-August).

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 60 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

Form B: Medical IRB Research Description

1. **Background:** The Tanglewood Trail walking group is a community-initiated walking group, spontaneously established in summer 2016. Community members meet at the Housing Authority in Whitesburg, KY and walk the approximately 1 kilometer Tanglewood Trail connecting the Housing Authority to the Farmer's Market. Participation in the walking group is open to the public. Participants that walk to the Farmer's Market on Wednesday evenings receive a $5 voucher to the Farmer's Market and a $10 voucher on Saturdays during the season (June-October). Adults 18 years and older receive one voucher each time they walk. Currently, there is no evaluation of the walking group program beyond the community tracking the name, number of walkers, and the number of vouchers distributed to walkers on each Wednesday and Saturday. This program was initiated by community members and UK researchers were not involved with its creation or tracking any component of the program.

   The current proposed study will target non-pregnant healthy, 18+ years old, community members who are willing and able to walk the Tanglewood Trail on Saturday mornings, June-August 2017. Community members will be randomized into a walking group and a farmers market group. Both groups will receive farmers market vouchers of equivalent value. One group will meet at the Housing Authority and walk to the farmers market to obtain their vouchers and the other group will obtain their farmers market voucher at the farmers market. Both groups are welcome to walk the Tanglewood Trail if they would like, however those that are randomized into the walking group are expected to walk. However, people are not forced to walk and have the option to refuse to walk. We hypothesize that adults who regularly attend the walking group and subsequently purchase fruits and vegetables at the Farmer's Market will experience an increase in physical activity, fruit and vegetable intake, and community engagement, and a decrease in anthropometrics and biomarkers associated with adulthood chronic disease (including cholesterol, hemoglobin A1c, blood pressure, carotenoid status, weight, and waist circumference) beyond that of the farmers market voucher group only.

2. **Objectives:**
   a) To educate Tanglewood Trail program participants about the health benefits of consuming a variety of fruits and vegetables, being physically active, and dietary strategies that can help protect their health from environmental pollution.
   b) Assess self-reported behavior change, knowledge change, and change in physical measurements (see below), and level of physical activity.

3. **Study Design:** The sample population consists of a convenience sample that is participating in a prospective study. This study will focus on nonpregnant healthy adult (ages 18+) community members who walk the Tanglewood Trail on Saturdays, June-August 2017.
   Any interested community members who are 18 years or older, nonpregnant and able to voluntarily give their consent are welcome to join the study. One hundred participants will be randomized into one of two groups – a walking group and a farmer's market group.
   The fifty participants randomized into the walking group will meet at the Housing Authority at a designated time each Saturday. When they arrive, they will be signed in by a community leader and receive a farmer's market voucher **(see attached)** for $10 along with education material (5 of the 13 Saturdays). They will walk as a group to the farmer's market and hand their voucher to the market manager, who will give them $10 in tokens to purchase fruits and vegetables at the market. The voucher will have two sides: one side will ask participants what fruits and vegetables they ate the past week; the second side will ask participants to check off what fruits and vegetables they purchase at the market that day. They will turn this in as they leave the market.
   The fifty participants randomized into the farmer's market group will meet at- the farmer's market and sign in with a UK employee. They will receive the same voucher and education materials and follow the same procedure as the walking group. Participants randomized into this group will be allowed to walk if they want; no one will be dissuaded from engaging in physical activity. However, in order to receive their voucher, it is not required for them to walk.
   Three times per month participants will be presented with education material concerning phytonutrients, the importance of fruit and vegetable intake, and how these factors might protect them from environmental pollutants. The education materials will be in the form of a.) a handout based on the Transtheoretical Model

(**see attached example**) or b.) Plate it Up Kentucky Proud recipe samples and cards (**see attached example**). A Registered Dietitian will be available to answer nutrition-based health questions once per month.

No participants will receive medications – neither real nor placebo.

Data will be a time series collection of finger-stick total cholesterol, LDL, HDL, triglycerides, hemoglobin A1c (cardiocheck meter), height, weight, waist circumference, carotenoid status (carotenoid RS, which is a non-invasive instrument that is a reliable indicator of fruit and vegetable intake **(see attached),** and a survey (**see attached**). Measurements will be taken twice – baseline data will be collected in May 2017, with follow-up data collected in early September 2017.

Finger stick tests will be conducted by University of Kentucky employees who have completed all necessary biohazard training (see attached IBC approval and certificates of completion). Lysol wipes will be available to wipe down equipment as needed. Hand sanitizer will be provided to each researcher to use between glove changes. Gloves will be changed between each participant. Heat packets will be available for participants with cold hands to make the finger stick go faster and easier. Lancets will be used to take the finger stick and all materials will be disposed of in sharps containers. All sharps containers will remain sealed until the research team returns to the University of Kentucky that same day to dispose of the sharps containers.

4. **Study Population:** Based on walking group numbers from summer 2016 we anticipate a maximum enrollment of 100 participants (18+ years old, nonpregnant). Previous research in Letcher County suggests the majority of participants will be white, ages 18-65, both male and female, of moderate health status. A prerequisite for participating in this study is the ability to walk approximately 1 kilometer to the Farmer's Market, nonpregnant, pre-supposing a baseline health status. Any interested community members over the age of 18 and in moderate or good health will be included. Since our focus is on changes in rates of chronic disease in adulthood, children will be excluded from study participation (but may walk the trail with their parents). Institutionalized adults, pregnant adults adults with impaired consent capacity, and prisoners will be excluded. No one will be excluded based on sex/gender or racial/ethnic identity.

5. **Subject Recruitment Methods and Privacy**: A community leader will build a facebook group in April 2017 to help recruit subjects. Interested participants will be invited to an opening baseline data collection event in May 2017. Interested participants will be told about the study and that their involvement is completely voluntary. We will obtain consent from those that are interested in participating in the study. We will then invite consented participants to fill out a survey and have the above measurements (see section 3) taken in return for a farmer's market t-shirt. Participants will be randomized into one of the two groups, walking group or farmers market only group, and informed of their group in May, during baseline measurements.

Privacy will be maintained through de-identification of all survey and measurement data. The surveys and measurement data sheets will contain a cover sheet that has a place to record the participant's name. The next page will be where the first question is listed and a space for the survey code to be recorded. Once the survey has been coded the cover sheet will be removed from the post-surveys and shredded. Participants will be asked to indicate which fruits and vegetables they purchased at the market on shopping card (**see attached**). The card will have a place for their name and they will give them to the community leader before leaving the market. The community leader will collect these weekly and give them to UK researcher bi-weekly. The shopping card data will be matched to participants' measurement data on an electronic datasheet. Once all of the data has been collected in September the electronic list of names will be replaced with a code to de-identify participants, the cover sheets of the surveys that contain participant names will be shredded and the surveys and shopping cards will be stored securely in a locked drawer in the PI's locked office. The electronic data that is generated will be stored on a password protected computer. Throughout the study, any study materials that contain participant names will be stored in a locked filing cabinet in the PI's locked office. In the event this data is published it will be done so by aggregating the data without identifying individuals.

Form B: Medical IRB Research Description

6. **Informed Consent Process**: All study personnel that will obtain consent are listed in Form A. Participants will be told they can decide to stop their participation at any time. The consent form will be read to any study participants with visual issues. UK study personnel will speak to study participants at an appropriate volume to be heard by study participants. Study personnel will ask if they are speaking loud enough, they will tell study participants to let them know when they need to speak up or slow down or repeat a question, and study personnel will be in tune to signs of study participants straining to hear.

   Consent will be obtained before physical measurements or survey data is collected. To obtain consent the UK study personnel will ask potential participants if they would like to participate in a research study that involves asking them questions about their health and diet and will also involve education material on phytonutrients, the importance of fruits and vegetables, and how these factors might protect them from environmental pollution. They will be told their participation is completely voluntary, and that they will be randomized into one of two groups. They will be informed that even if they are randomized into the farmer's market group, they are still allowed to walk whenever and however often they like. Those randomized to the walking group will be told that they are expected to walk each Saturday morning, but they will never be forced to walk and will be encouraged to abstain from walking on Saturdays when they do not feel well. They will also be told their survey answers will not be reported individually or with their name, but as anonymous aggregated data. Additionally, they will be told their participation is voluntary and they can withdraw from the study at any time and they do not have to answer any questions that they are not comfortable answering. If the participant agrees the consent form will be given to them and their signature obtained. The participant will be given a copy of an investigator-signed consent form.

   The UK study personnel will ask if the participant would like to move elsewhere to complete the survey and anthropometric/biological data collection. Study personnel will also explain that the consent forms and surveys will be stored separately in a locked drawer in the PI's locked office and that an electronic file will be created that lists their name and survey code. This list will be destroyed following the collection and entry of post-survey data. Any electronic files generated from this study will be stored on a password protected computer.

   Obtaining consent and completing the survey will take approximately 15 minutes. An additional 30 minutes will be needed to complete the anthropometric and biological measurements.

   The midline and post data will be collected in the same manner as the pre data. The UK study personnel will offer the same explanation of the survey and anthropometric/biological measurements and the same procedures will be followed, consent however will not be obtained again. The midline and post-surveys will contain a cover sheet that has a place to record the participant's name. The next page will be where the first question is listed and a space for the survey code to be recorded. Once the survey has been coded the cover sheet will be removed from the midline and post-surveys and shredded once all data has been entered electronically.

7. **Research Procedures:** Following IRB approval, beginning in May 2017 community members will show up to a designated location approximately 1 kilometer from the Farmer's Market. Participants will fill out a survey and have anthropometric and biological measurements taken. Carotenoid status will be measured via carotenoid RS scanner. Anthropometric data will be collected by UK researchers and include weight (digital scale), height (portable stadiometer), waist circumference (tape) and blood pressure (digital blood pressure machine) Finger stick tests will be conducted by University of Kentucky employees who have completed all necessary biohazard training. Lysol wipes will be available to wipe down equipment as needed. Hand sanitizer will be provided to each researcher to use between glove changes. Gloves will be changed between each participant. Heat packets will be available for participants with cold hands to make the finger stick go faster and easier. Lancets will be used to take the finger stick and all materials will be disposed of in sharps containers. All sharps containers will remain sealed until the research team returns to the University of Kentucky that same day to dispose of the sharps containers.

In June through August 2017, participants in the walking group will continue to show up to the same location, be signed in by a community member, and walk approximately 1 kilometer to the Farmer's Market, in exchange for $10 they can spend at the market. Participants in the farmer's market group will show up to the farmer's market, be signed in by a UK employee, and follow the same voucher protocol as the walking group. Three Saturdays of each month, participants from both groups will receive education material in the form of a.) handouts based on the Transtheoretical Model or b.) Plate it Up Kentucky Proud recipes samples and cards. A Registered Dietitian Nutritionist will be available at least one weekend of each month to answer nutrition-related questions.

Post-data will be collected in September 2017; the same survey will be administered and participants will again have their anthropometric and biological measurements taken.

No clinical care will be given as a part of this research study.

8. **Resources:**

PI – Dawn Brewer, PhD, RDN, LD
Program Manager – Annie Koempel, RDN, LD
Research assistant – Kelci McHugh
Undergraduate research assistants
Community Leader
Community Stakeholder

The PI, program manager, and research assistant will be responsible for all data collection and analysis. All education materials will be developed by the program manager and research assistant with oversite by the PI. The program manager and undergraduate research assistants will be USDA Good Agricultural Practices (GAP) trained to serve Plate it Up Kentucky Proud samples at one Farmer's Market per month. Undergraduate research assistants will also assist in data entry as needed (they will complete CITI certification and be added to research personnel list before having access to data). The PI will provide guidance through the process. The PI has space to store all of the consent forms, paper surveys, shopping cards and measurement data sheets in a locked drawer in the PI's locked office. All UK study personnel have computers and statistical analysis software to carry out research procedures, which are all password protected to secure any electronic files that are generated from this study. The PI has funds to purchase paper and food supplies and transportation to conduct the study.

In the event that unanticipated problems or noncompliance issues occur or the situation arises that requires submission of protocol modifications or interim results, the PI will first consult the Office of Research Integrity's website to determine action steps appropriate to the issue. If the PI still has questions she will contact the Office of Research Integrity to obtain the appropriate protocol to resolve a situation.

9. **Potential Risks:**

No physical, psychological, social, legal, cultural, or financial risks can be perceived from participating in this research. In the rare case that a dangerously high blood pressure or hemoglobin A1c is recorded, the participant will be referred immediately to the local emergency department for care. All foods prepared for the farmer's market will be accompanied by a recipe card with ingredients. Potential allergens will be identified and communicated to all participants. Participants will not be forced to taste any food. Undergraduate research assistants will be GAP trained and knowledgeable about food safety issues. No participants will be discouraged from walking to the farmer's market, regardless of which group they are randomized into. The only difference between the two groups is where they sign in; the walking group signs in 1 kilometer from the market, while the farmer's market group signs in at the market.

Finger stick tests will be conducted by University of Kentucky employees who have completed all necessary biohazard training. Lysol wipes will be available to wipe down equipment as needed. Hand sanitizer will be provided to each researcher to use between glove changes. Gloves will be changed between each participant. Heat packets will be available for participants with cold hands to make the finger stick go faster and easier. Lancets will be used to take the finger stick and all materials will be disposed of in sharps containers. All sharps containers will remain sealed until the research team returns to the University of Kentucky that same day to dispose of the sharps containers.

A potential risk is a breach of confidentiality, which is minimal due to the study being voluntary, removing the signed consent form from the coded survey, shredding the cover sheet that contains names on the post-surveys, storing shopping cards in a locked drawer in the PI's locked office, deleting the document containing participant names and codes once the post-survey data has been coded, using a password protected computer, and storing any hard copies of study-related material in a locked drawer that is in a locked office.

10. **Safety Precautions:** Participation in every aspect of the intervention is voluntary. Participants do not have to respond to any survey questions that they are uncomfortable answering or participate in any anthropometric or biological measurements they are uncomfortable with. No one will be discouraged from engaging in physical activity.

When identifiable data (names) is being collected it will be on the cover sheet or consent form of a survey and will be detached from survey data that will include a code that is linked to the participant. At the end of the study, the cover sheets will be deleted and consent forms will be stored separately from the surveys in a locked drawer in the PI's locked office. The electronic list containing the names and survey codes will be deleted once all post-survey data is entered, which will be entered within a month following collection. However, the assigning of codes, and generating the electronic document that lists codes and names from surveys will occur the day of data collection at UK.

The study population consists of adults ages 18 years or older who are in good enough health to walk 1 kilometer to the farmer's market.

Finger stick tests will be conducted by University of Kentucky employees who have completed all necessary biohazard training. Lysol wipes will be available to wipe down equipment as needed. Hand sanitizer will be provided to each researcher to use between glove changes. Gloves will be changed between each participant. Heat packets will be available for participants with cold hands to make the finger stick go faster and easier. Lancets will be used to take the finger stick and all materials will be disposed of in sharps containers. All sharps containers will remain sealed until the research team returns to the University of Kentucky that same day to dispose of the sharps containers.

11. **Benefit vs. Risk:** Potential benefits include (but are not limited to) a decreased risk for high blood pressure, high blood glucose, and cardiovascular disease; a decrease in oxidative stress; a decrease in generalized inflammation; an increase in community engagement; an increase in physical activity, and an increase in overall fruit and vegetable consumption.

There is no more than minimal risk to participants in this intervention with the benefits outweighing any risk. There is however, a potential risk of a breach in confidentiality, which is minimal due to the study being voluntary, removing the signed consent form/cover sheet from the coded pre/post surveys, deleting the document containing participant names and codes once the post-survey data has been coded, shredding the cover sheets attached to post-surveys with participants names, using a password protected computer, and storing any hard copies of study-related material in a locked drawer that is in a locked office.

12. **Available Alternative Treatment(s):** N/A

Form B: Medical IRB Research Description

13. **Research Materials, Records, and Privacy:** Participants will be asked to fill out two surveys (May and September 2017). The surveys contain questions about demographics, self-reported health, physical activity, fruit and vegetable consumption, and community engagement.

Participants will be asked to complete weekly shopping cards that will require them to mark which fruits and vegetables they purchased at the farmer's market and what fruits and vegetables they ate over the past week.

Participants will be asked for finger-stick total cholesterol, LDL, HDL, triglycerides, hemoglobin A1c (cardio check meter), height, weight, waist circumference, and carotenoid status (carotenoid RS, which is a non-invasive instrument that is a reliable indicator of fruit and vegetable intake) twice (May and September 2017).

The collected data will be collated and summarized without identification or attribution to the individual participants. All reports will only reveal aggregated summaries across participants. The surveys with attached consent forms will be collected and stored separately in a locked drawer in the PI's locked office. An electronic document containing participant name and code will be generated and stored on a password protected computer. Following the collection of post-survey data and coding of the post-survey data the electronic document containing the names and codes will be deleted. To minimize risk of identification the consent forms will be removed from the survey and the survey will have a code written on it. The consent forms, shopping cards and surveys will not be stored together, but both will be in a locked drawer.

The information collected will be used to assess whether walking 1 kilometer to the farmer's market and spending approximately $10 at the market improves physical activity, fruit and vegetable intake, community engagement, and chronic disease-related biomarkers (i.e. cholesterol, A1c, etc).

14. **Confidentiality:** The collated data 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 in a locked drawer within a locked office or on a password protected computer. The PI and program manager assigned to the project and involved in data collection will have access to these items.

15. **Payment**: Participants will be offered a farmer's market t-shirt at the baseline data collection time (May 2017) and a $10 gift card at post-data collection (September 2017) as well as the weekly $10 voucher to the farmer's market.

16. **Costs to Subjects**: N/A

17. **Data and Safety Monitoring:** N/A the study does not have greater than minimal risk.

18. **Subject Complaints:** Participants can voice their concerns to the PI, Co-PIs, program manager, or the Office of Research Integrity, which is listed on the consent form.

19. **Research Involving Non-English Speaking Subjects or Subjects from a Foreign Culture:** N/A

20. **HIV/AIDS Research:** N/A

21. **PI-Sponsored FDA-Regulated Research:** N/A

Tanglewood Trail Walking Program in Rural Kentucky 2020 - SAP

A dependent t-test will be used for the difference in survey questions (environmental pollution knowledge, fruit and vegetable intake, and physical activity) between before and after the Tanglewood trail walking program.

When the sample size is 50, a dependent t-test with a 5% two-sided significance level will have 80% power to detect an effect size of 0.4 calculated from previous data.