VUMC Institutional Review Board
Informed Consent Document for Research

Study Title:	Whole Foods for Teens: A Pilot Dietary Intervention to Reduce Body Adiposity in Adolescents with Obesity
Version Date:	10/01/2025
PI:	Nadia Markie Sneed PhD, APRN, FNP-BC

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

Key Information:
The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:
This 8-week study aims to understand if adolescents and their families want to learn to eat healthy meals together, and if eating healthy foods can support a healthy weight in adolescents and improve diet quality in families.

Participants will be randomly assigned to one of two groups:

1. **Whole Teens Counseling Group**: Participants will meet with a Registered Dietitian Nutritionist up to 3 times to learn about using MyPlate and following a healthy diet pattern.
2. **Whole Teens MyPlate Group**: Participants will receive a personalized MyPlate plan and be asked to follow it for 8 weeks. They will meal plan, prepare, and cook healthy foods for the family, and eat together at home as often as possible. Participants will meet with a Registered Dietitian Nutritionist every 2 weeks to ask questions about the diet plan. They will also participate in a focus group session to provide feedback on the program.

All participants will be asked to:

- Complete surveys and answer detailed questions about their and their adolescent's diet at two in-person visits (120-180 minutes each).
- Have their weight, height, and waist circumference measured.
- Adolescents will complete two body composition scans (DXA) at the beginning and end of the study.
- Use a food diary to report the foods they ate on some days during the program.

The total time commitment for the Whole Teens MyPlate group is estimated to be 2-4.5 hours weekly, plus 1-2 hours daily for meal preparation. For the Whole Teens Counseling group, the total time

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commitment is estimated to be 10-12 hours. There will be no costs to participants, and the research team does not believe the study poses any risks.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

You are being asked to take part in this research study because you indicated that you are 25 years or older, have at least one metabolic condition (e.g., high blood pressure, hyperglycemia, overweight or obesity, etc.), are a parent or legal guardian of an adolescent age 10-18 years with a body mass index (BMI) at or above the 95th percentile for age and gender, and live at home full-time (≥80% of the time) with the enrolled adolescent.

We are doing this study to understand if adolescents and their families want to learn to eat healthy meals together and if eating healthy foods can support a healthy weight in adolescents. Also, we want to learn if eating whole foods can make families' diets better.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study.

Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

Side effects and risks that you can expect if you take part in this study:
We do not believe that being part of this study puts you or your family at significant risk. However, there are a few potential risks to be aware of:

- **Food Allergies:** There is a small possibility that trying new foods could result in a food allergy reaction. If this occurs, we ask that you seek immediate medical attention and notify the study team as soon as possible.
- **DXA Scans [Females Participants ONLY]:** Your adolescent will be asked to complete two whole-body DXA scans to measure their body composition. These scans are quick, painless, and use a low-dose X-ray. However, DXA is not safe in pregnancy, and we may ask for a urine pregnancy test prior to completion of each DXA scan.

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- **Confidentiality:** There is a risk of potential loss of confidentiality related to the information you provide. However, the research team will take every precaution to protect your personal information.
- **Discomfort:** You may feel uncomfortable answering some of the survey questions, but you can choose not to answer any questions that make you feel uncomfortable.

Overall, the research team does not anticipate any serious or long-term risks from participating in this study. However, please let the study team know if you have any concerns or experience any adverse effects.

Good effects that might result from this study:

1. **The benefits to science and humankind that <u>might</u> result from this study.** This study may help us learn if adolescents and their families want to learn to eat healthy meals together and if eating healthy foods can support a healthy weight in adolescents. Also, we may learn if eating whole foods can make families' diets better.
2. **The benefits you might get from being in this study.** You and your family may learn about how to choose, prepare, and eat healthy foods.

Procedures to be followed:

This 8-week study will involve the following procedures:

In-Person Visits:

- You and your adolescent will be asked to attend two in-person visits at the Vanderbilt University campus, each lasting 120-180 minutes.
- During these visits, you will complete surveys and answer detailed questions about your and your adolescent's diet.
- Your weight, height, and waist circumference will also be measured using a digital scale, a standing height measurer (i.e., stadiometer), and a tape measurer.

Group Assignments:

- You will be randomly assigned to one of two groups:
    1. Whole Teens Counseling group:
        - You and your adolescent will meet with a Registered Dietitian Nutritionist up to 3 times to learn about healthy eating using the USDA's MyPlate guidelines.
        - You will be asked to complete a 3-day food diary before starting the study and then every 2 weeks during the program to track your dietary habits. You will be required to upload this information using the secure research application, MyCap.
    2. Whole Teens MyPlate group:

- You will receive a personalized MyPlate plan and be asked to follow it for 8 weeks.
- You will meet with the Registered Dietitian Nutritionist 4 times (1-2 hours each) to discuss meal planning, preparation, and nutrition.
- You will be provided with some groceries to help you meet your MyPlate goals.
- You will be asked to complete a 3-day food diary before starting the study and then every 2 weeks during the program to track your dietary habits. You will be required to upload this information using the secure research application, MyCap.
- You will be asked to complete brief survey questions 3 times during the study to share your perceptions of the whole foods intervention. You will be required to upload this information using the secure research application, MyCap.
- At the end of the study, you and your adolescent will participate in a 2-2.5-hour family focus group session.

DXA Scans:

- Your adolescent will be asked to complete two whole-body DXA scans, one at the beginning and one at the end of the study.
- The DXA scan uses low-dose X-ray technology and takes about 10-20 minutes to complete.
- The total appointment time is estimated to be 30 minutes to 1 hour and can only be scheduled Monday – Friday between 8am and 4 pm.
- We will ask if your adolescent has had any recent procedures using contrast materials, as this may require rescheduling the DXA scan.
- Your adolescent may be asked to wear a hospital gown and remove any jewelry, eyeglasses, metal dental appliances, or other objects that could interfere with the X-ray equipment.

The diet for this study is based on the healthy eating recommendations from the U.S. Department of Agriculture's Dietary Guidelines for Americans. During the study, you and your adolescent will receive a personalized MyPlate eating plan. This plan will help you and your adolescent meet your daily food group goals based on your recommended calorie needs (the amount of energy from food your body needs based on your current height and weight).

The diet plan will follow calorie recommendations that are appropriate for your age and gender. It will specify the recommended amounts of carbohydrates, fats, and proteins you should eat each day. The plan will aim for:

- 45-50% of calories from carbohydrates
- 30-35% of calories from fats
- 20-25% of calories from proteins

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The diet will also limit added sugars and saturated fats, and avoid "junk foods" and sugary beverages. Menus will be provided to help you, and your adolescent meet the recommended intakes of carbohydrates, fats, and proteins.

How we will communicate with you during/after the study:
If you agree, our research staff may contact you by text, call, email, or mail to discuss the study and/or schedule a time for us to call you to complete surveys. We would like to ask for your permission to keep in touch in case we have another phase of this study or future studies that you and your family may be interested in. You can decide later if you want to participate in those. If you allow us to stay in contact, we may ask you to update your phone numbers, address, and emergency contacts, in case we have trouble reaching you. We may call, text, or send you updates by mail or email. This is optional - you can choose whether to allow us to stay in touch at the end of this form.

In this study, we will collect data using a mobile application (app) called MyCap. This app will need to be downloaded to your mobile device (iOS or Android). You will receive an email or text from our research team that will include a QR code and/or hyperlink to download the application on your mobile device. All data collected in the MyCap app is automatically sent back to the system where the research team stores data. Data collected via MyCap will live on your device or in the research system, and it will not be sent to third parties. Data charges may apply when using MyCap as this app requires internet connection to send and receive data. You can send messages to the research team via the MyCap app. Do not use MyCap to send messages for urgent contact. Contact the study team directly using the information provided to you in the consent form for emergencies. We will use this app to send push notifications and reminders for you to submit your completed food diary records. Participants in the Whole Teens MyPlate group will be asked to complete some brief survey questions about their perceptions of the whole foods intervention.

Payments for your time spent taking part in this study or expenses:
If you agree to take part in this research study, you and your adolescent will be compensated for your time and could receive kitchen tools (for completing the baseline visit), a personal blender (for completing the baseline DXA scan), and monetary compensation between $100 to $130 for completing all remaining study requirements as follows: a) up to $50 for completion of food diaries and MyPlate plans, b) $25.00 for attending and completion of height, weight, waist circumference and survey collections at the 8-week follow-up visit , c) $25.00 for completing the final DXA scan, and d) $30 for attending the focus group session (for Whole Teens MyPlate group only). Payment will be received in the form of an electronic gift card (bank deposit for foreign nationals) within 2-4 weeks upon the completion of the necessary payment documentation.

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Table 1.		
Study Time Points for Data Collection	**Completing of all Baseline Requirements**	**About How Long Data Collection Will Take**
Baseline	**Kitchen tools** for completion of baseline visit requirements (e.g., surveys/questionnaires, anthropometry collection) **Personal blender** for DXA scan completion **Total Possible Compensation: $0.00**	120-180 minutes 90-120 minutes per collection
Study Completion (weeks 1-10)	$50 for completion of 8 weeks of dietary information (e.g., 3-day food diaries via MyCap, MyPlate plans, Diet Feasibility/Acceptability Survey) or $25 if only 4 weeks of dietary information is completed $25 for completion of follow-up visit requirements (e.g., surveys/questionnaires, anthropometry collection) $25 for DXA scan completion **Total Possible Compensation: $100**	10 minutes per collection 120-180 minutes 90-120 minutes per collection
Family Focus Group (**Intervention only**-group)	$30 (requires adolescent and enrolled parent/caregiver) **Total Possible Compensation: $30.00**	120-150 minutes

All participants who wish to accept payment for their participation will be required to submit a payment form that requests personal information (e.g., name, address, email, phone, citizenship status, etc.).

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Study payments given to VU employees count as taxable income and will be reported to VU by study personnel to be included on Form W-2. If you receive $600 or more from the university in a calendar year, VU must report the amount you receive to the Internal Revenue Service (IRS) on the form 1099-MISC. This form tells the IRS that payment was made to you, but it does not say that you were paid for taking part in this research study. You should talk to your tax advisor regarding the proper use of this form 1099-MISC.

In addition to the payment form, foreign nationals receiving payment will be required to register as a VU supplier and complete a GLACIER record prior to receiving payment as federal and state tax withholdings apply. Payments made to human subjects who are foreign nationals are reported on Form 1042-S. All payments to foreign nationals are subject to 30% federal income tax withholding and sent via direct deposit.

You are not allowed to accept any money for taking part in this study if you are not eligible to receive money from a U.S. person or company or the U.S. government because of U.S. national security and/or foreign policy laws. You can still take part in the study; however, you will not be paid if you are a resident of a country restricted by the U.S. government's comprehensive territorial sanctions or if you are listed on the U.S. Treasury Department's Office of Foreign Assets Control's Specially Designated Nationals (SDN) list of prohibited individuals. You do not have to say why you choose not to be paid.

Costs to you if you take part in this study:
There is no cost to you for taking part in this study.

Payment in case you are injured because of this research study:
If it is determined by Vanderbilt and the Investigator that an injury occurred, then you and/or your insurance may be billed for the cost of medical care provided at Vanderbilt to treat the injury. You will be responsible for any copayments or deductibles associated with the treatment of that injury.

There are no plans for Vanderbilt to pay for the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

Circumstances under which the Principal Investigator may withdraw you from study participation:
We do not plan to ask participants to stop being in the study. If we decide to ask you to stop being in the study (withdraw you from the study), we will let you know why we decided to do this.

What happens if you choose to withdraw from study participation?

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You may stop being in (withdraw from) the Whole Food for Teens study at any time. You may stop being part of the study at any time and for any reason, without this causing any problem for you. Any research data collected before you took back (withdrew) consent may still be used for reporting and research quality. Research data collected will be stored for at least 3 years.

Who to call for any questions or in case you are injured:
If you should have any questions about this research study or possibly injury, please feel free to contact the Principal Investigator, **Dr. Nadia Sneed** at **615-343-2302.**

For additional information about giving consent or your rights as a participant in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to contact the Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Clinical Trials Registry:
A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This website 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.

Confidentiality:
All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed. Your study information will be kept on paper records and on a computer database. The paper records will be kept in locked cabinets. Each person in the study will be given a number to identify you in the place of your name. The computer records will only include this number and will be on a secure site (safe place) that only people on the study team can get to. Only the Principal Investigator and certain research staff will be able to get to your information and to the file that links your number with your name, which will also be on a secure site (safe place) on the computer. We will not include your name or any identifying information in any reports we write about this study.

After we remove all information that could identify you or your **adolescent**, your data may be shared with a third party for analysis.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

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Certificate of Confidentiality Language:
This study may have some support from the National Institutes of Health (NIH). If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Privacy:
Your information may be shared with Vanderbilt or the government, such as the Vanderbilt University Institutional Review Board or Federal Government Office for Human Research Protections if you or someone else is in danger or if we are required to do so by law. Vanderbilt may give or sell your data without identifiers for other research projects not listed in this form. There are no plans to pay you for the use or transfer of this de-identified information.

Study Results:
After we have finished the study, we may write a report and tell others about what we have learned. We will not use your name or your **adolescent** name in the report when we tell others what we have learned.

Authorization to Use/Disclose Protected Health Information
What information is being collected, used, or shared?
To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?
The people who may request, receive or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors, outside providers, study

safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your healthcare providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

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STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

Date _____ Signature of patient/volunteer _____

Consent obtained by:

Date _____ Signature _____

Printed Name and Title _____

May our research team contact you in the future for potential participation in another phase of this study or for potential participation in different research studies?

- ☐ **YES,** you may contact me in the future for potential participation in another phase of this study or for potential participation in different research studies.
- ☐ **NO,** you may not contact me in the future.