Whole Food for Families: A Pilot RCT of a Dietary Guidelines-Based Intervention to Prevent Type 2 Diabetes

NCT06482944

VUMC Institutional Review Board
Informed Consent Document for Research

Study Title:	Whole Food for Families: A Pilot RCT of a Dietary Guidelines-Based Intervention to Prevent Type 2 Diabetes
Version Date:	09/08/2025
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 study will last for 14 weeks. Being in the study will result in no costs to you. We do not believe that being part of this study puts you at risk. This study will help us learn if adults with prediabetes and their children are interested in participating in and following a healthy diet and if this diet can prevent a condition known as Type 2 Diabetes in adults. You and your child will be put in one of two groups. If you are in the *Whole Foods Counseling* group you will meet with a Registered Dietitian Nutritionist one time to talk about how to help you and your family follow a healthy diet pattern. If you are in the *Whole Foods Healthy Eating* group we will give you and your family food for 8 weeks to cook and eat and we will ask that your family participates in the meal planning, preparation, and cooking (as age appropriate). We will also ask you to eat meals together as a family. You will have the opportunity to ask the Registered Dietitian any questions you may have about your diet plan. After 8 weeks, we will ask you to continue the diet program on you own for the last 4 weeks of the program. If you are in the *Whole Foods Healthy Eating group*, you will be asked to provide a small at-home stool sample two times during the study. We will also ask you to wear a continuous glucose monitoring device to measure your blood glucose (sugar) levels for 15-days three times during the study.

We will ask everyone in the program to use a food diary to tell us what foods they ate during the program. You will be asked to meet in person two times (120-180 minutes each session). At each visit, we will ask you to complete surveys and we will ask some detailed questions about you and your child's diet. We will also measure you and your child's weight, height, and waist circumference and we will collect a blood sample from your finger two times in the study to measure your prediabetes levels. We will also use a portable face mask device called an indirect calorimeter (Breezing Med™) at the

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beginning and end of the study to estimate your average calorie needs. We will also ask you to participate in a one-time focus group session with other families to ask what you learned and what you liked or did not like about the study. We estimate that the total time commitment of this study is 2 to 4 ½ hours weekly (up to 54 hours total) plus time to prepare and cook meals (about 1-2 hours daily) if you are in the *Whole Foods Healthy Eating* group. We estimate that the total time commitment of this study is 8-10 hours total if you are in the *Whole Foods Counseling* group.

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 have prediabetes and are a parent of a child ages 6-18.

We are doing this study to learn if adults with prediabetes and their children want to eat healthy meals together as a family and if eating healthy foods can make families' diets better. We also want to learn if eating healthy can prevent a condition called Type 2 Diabetes in adults.

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 at risk. The main inconvenience to you will be the time commitment required for the study.

Food allergy risk: There is a possibility that with trying new foods, a food allergy could occur. We believe this is unlikely; however, in the event that you, your child, or a non-enrolled family member develops a new food allergy reaction while participating in this study, we ask that the affected person seeks immediate medical attention. We will also ask that the affected person stops eating any foods provided from the study and that you contact a member of our study team to let us know about the incident as soon as possible.

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Finger stick: You may experience discomfort or pain at the site of a finger prick related to prediabetes testing. Sometimes redness, soreness, bruising, or infection may occur at the needle stick site. Rarely, some people faint. Pressure will be applied with a clean gauze at the site to reduce the sensation of discomfort/pain. While unlikely, there is a possible risk of infection at the site of the finger prick. To limit this risk, we will clean the area with a sterile alcohol pad prior to collecting our sample and we will use a single-use sterile lancet device to collect the blood sample. Afterwards, a bandage will be applied to the site to keep the area clean. The risk for infection is very low, however you will be asked to report any signs of infection to the study team and to seek medical treatment in the event of a potential site infection.

Stool collection: Although stool collection is non-invasive, there might be risk of skin irritation or infection by parasites or agents in stool or collection tubes (rare) if coming in contact with stool.

Continuous glucose monitoring (CGM): When the sensor is inserted, you may experience discomfort or pain at the site (back of upper arm or lower abdomen). After insertion, you may feel some tenderness, but you should not feel any large amount pain. Pain, redness, swelling, and minor bleeding at the sensor insertion site (<10%) are possible risks with use of the device. In very rare cases an infection might spread to other parts of the body. Significant or serious health risks with the study device are not expected. The device is FDA-approved for use in patients with diabetes. Redness may occur where the adhesive pads are placed. This will occur in most research participants and will clear up no more than a week after removal. You may develop an allergic reaction to one or more parts of the sensor and transmitter (<10%). This is like allergies that occur due to hospital tape or jewelry. Allergic reactions will usually be mild and require only a skin cream to make them better. Major allergic reactions are rare. If you have an allergic reaction, you should notify the study researcher or study staff. On rare occasions, the sensor may cause skin to blister or peel. If this happens you should notify the study staff as soon as possible. There is a chance that the sensor or needle may break. This is not expected to occur. Sterile detached sensor wires usually don't pose a significant medical risk. If a sensor wire breaks off or detaches, remains under your skin, and shows signs of infection or inflammation, please contact our study team and we will ask you to see your healthcare provider for an appointment. If there is no sign of infection or irritation and you cannot see the sensor above the skin, it is not recommended to remove it. The radio waves that the study device puts out will not hurt you and you will not be aware of them.

Indirect calorimeter (Breezing Med™) device: There are no known risks associated with the use of the Breezing Med™ indirect calorimetry device. Because the device requires the use of a tight-fitting face mask around the nose and mouth, some people may experience claustrophobia or feel uncomfortable.

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If this occurs, you will be provided with time to adjust to the mask before testing begins. If severe, you will be allowed to refuse use of the device. If you are sick with an upper respiratory infection during your appointment, you may be asked to reschedule another visit so we can complete your indirect calorimetry testing when well.

Surveys: You may feel uncomfortable about some of the questions on the surveys, but you can decide not to answer any questions that make you feel uncomfortable.

Confidentiality: There is the risk of potential loss of confidentiality from an unintended data breach. However, we will protect this information as best we can, as described below.

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 adults with prediabetes and their children are interested in participating and following a healthy diet and eating together as a family and if eating healthy foods can make families' diets better. We also hope to learn if eating a healthy diet may prevent a condition called Type 2 Diabetes in adults and how it influences gut bacteria.

2. **The benefits you might get from being in this study.** You and your child may learn about how to choose, prepare, and eat healthy foods.

Procedures to be followed:

This study will last for 14 weeks. We estimate that the total time commitment of this study is 2 to 4 ½ hours weekly (up to 54 hours total) plus time to prepare and cook meals (about 1-2 hours daily) if you are in the *Whole Foods Healthy Eating* group. If you are in the *Whole Foods Counseling* group, we estimate that the total time commitment of this study is 8-10 hours total.

Prior to Randomization: During the study, you and your child will learn about eating healthy meals together as a family. Once you are enrolled in the study, we will ask you to meet in-person with your child two times for up to 2 ½ hours each time at our facility on Vanderbilt University's campus. NOTE: If you are in the *Whole Foods Healthy Eating group*, we may ask you to come an additional 1-2 times if you are having trouble placing your Continuous Glucose Monitoring Sensor.

During your first visit and follow-up visit, you will complete surveys about you and your family's dietary habits, and you and your child's physical activity levels. We will measure you and your child's height, weight, and waist at each visit. We will estimate your calorie requirements at each visit using an indirect

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calorimeter device called Breezing Med™. This device is a portable facemask that fits over your nose and mouth. You will be asked to wear the device for 10-15 minutes. We will ask you to come to your appointment fasting to ensure testing accuracy (no food over an 8-hour period prior to your visit or only a light meal of ~500 calories 4-hours prior to your visit). During testing, you will be placed in a quiet room without distractions (e.g., no cellphones) and we will ask you to sit upright in a comfortable chair while remaining calm and still during the testing. You will be asked to either watch a 10-minute calming scenic video on our iPad or listen to calming music during your testing to help you stay relaxed. After testing, our research staff will go over how to collect your dietary recall information, and we will provide details for downloading the MyCap app to use during the study. At the end of the study, we will invite you and your child to participate in a one-time 2 to 2.5-hour focus group session with other families to ask you what you liked or did not like about the study and what you learned. All focus groups will be recorded with either an audio recorder or a secure teleconference platform so we can listen to them at a later date to gather information about what participants thought about the study. Because the focus groups will take place in a setting with other participants, we will not be able to keep your identity confidential from the group. However, information collected during the focus group session will remain confidential and will only be accessible by the Principal Investigator and study team members.

You and your child will be randomly selected to participate in one of two groups:

1. *Whole Foods Counseling* group: If you and your child are asked to be in the *Whole Foods Counseling* group:
    - We will ask you to meet with a Registered Dietitian Nutritionist one time over the phone or via a secure web-based platform (e.g., Zoom, Microsoft Teams) to learn about how to eat a healthy diet pattern. The dietitian will create an individualized diet plan for you and your child to follow that is based on the United States Department of Agriculture (USDA) Healthy Diet Pattern.
    - You will fill out a food diary for 3 days at the beginning of the study and 5 times during the study period to learn more about your family's dietary habits.
    - You will complete the Daily Eats diet questionnaire at weeks 1, 2, 4, 8, and 10 to report your levels of fullness and appetite.
    - You will complete the Diet Feasibility/Accessibility questionnaire at weeks 2, 6, and 12 to describe your thoughts on the diet.
    - You will record your weight weekly at weeks 1-12.

2. *Whole Foods Healthy Eating* group: If you and your child are asked to be in the *Whole Foods Healthy Eating* group:

- We will send food to your home weekly for 8 weeks and ask you and your family to cook healthy meals together.
- You will meet with a Registered Dietitian Nutritionist weekly to bi-weekly during the first 8 weeks. The meeting will be conducted over the phone or via a secure web-based platform (e.g., Zoom, Microsoft Teams). The Registered Dietitian Nutritionist will help you plan what to eat each week and will discuss how to plan, prepare, and cook the foods provided to you and your family.
- You will be asked to fill out a daily checklist for the first 2 weeks to tell us what you and your child ate and drank each day.
- You will fill out a food diary 3 days per week 4 times during the study. You will upload this information into the MyCap app or send reports to the study dietitian to help him/her understand more about you and your child's diet during the study. Each session with the dietitian will take between 1-2 hours.
- You will complete the Daily Eats diet questionnaire at weeks 1, 2, 4, 8, and 10 to report your levels of fullness and appetite.
- You will complete the Diet Feasibility/Accessibility questionnaire at weeks 2, 6, and 12 to describe your thoughts on the diet.
- We will provide you with a scale, and you will record your weight weekly at weeks 1-12 either in the MyCap app or report/send an email to the Registered Dietitian.
- During the study, we plan to have all groceries delivered to your home or we may ask you to pick them up at our VUSN Research Laboratory if you live outside of the delivery zone. Groceries will be provided at no cost to you and your family using a grocery delivery service (e.g., Shipt, Kroger).
- During the first two weeks, we will send enough food to your family to prepare three meals and 1-2 snacks per day.
- During weeks 3 through 8 of the study, you and your family will be asked to pick three dinner menus from a list based on your liking. We will send these foods to your homes to help you prepare these meals each week.
- In the last four weeks of the study, we will ask you to continue using the menus and continue eating the whole foods diet pattern on your own without us sending food to your home or scheduling meetings with the Registered Dietitian Nutritionist.
- At the end of the study, we will invite you and your child to attend an optional 2-2 ½ hour family focus group session. During the focus group session, we will gather information about your participation in the study and ask you and your family what you thought about the Whole Foods program. All focus groups will be recorded with either an audio recorder or a secure teleconference platform so we can listen to them at a

later date to gather information about what participants thought about the study. Because the focus groups will take place in a setting with other participants, we will not be able to keep your identity confidential from the group. However, information collected during the focus group session will remain confidential and will only be accessible by the Principal Investigator and study team members.

The diet for this study is based on the United States Department of Agriculture diet recommendations provided in the 2020-2025 Dietary Guidelines for Americans report. The Dietary Guidelines for Americans provides evidence-based recommendations for a healthy diet for all children and adults living in the United States. During the study, you and your child will receive individual instructions from our study team about how many calories from foods you will need to eat daily. This will be based on how much energy from food your body needs to maintain your current weight. The diet will follow calorie recommendations that are based on age and gender groups. The diet will be broken down into how many calories from carbohydrates, fats, and proteins you need to eat daily and will include 45% of each day's calories from carbohydrate foods, 30% of each day's calories from dietary fats, and 25% of each day's calories from protein. The diet will have low amounts of added sugars and saturated fats and no "junk foods" or sugary beverages. Menus will be created to help you and your child follow recommended intakes of carbohydrates, fats, and protein each day.

Stool sample: You will be asked to self-collect a small stool sample at home and mail (using a provided shipping label) or return (in-person) the sample and collection form to the Vanderbilt University School of Nursing 2 times during the study. The information collected from the stool sample will allow us to examine the role of your gut bacteria while participating in our study. With each collection, you will need to complete a brief ~5-10-minute survey about your lifestyle habits and medical history that you will upload via MyCap or returned to our lab during your final in-person visit.

Continuous Glucose Monitoring: You will be asked to wear a 15-day continuous glucose monitoring device 3 times during the study. This device will be used to collect information each day about your blood glucose (sugar) levels during the study. You will be required to download the study specific phone-based app to activate the device (minimum requirement iOS 16.2 and Android 12 required) and will be asked to follow the manufacturer instructions for use. This device will allow you to monitor your glucose readings. The Dexcom System includes a small sensor (about the size of a quarter). The sensor includes a probe that is flexible and thicker than a strand of a human hair and is about a 1⁄2 inch long. The needle is slightly thicker and the same length as most insulin syringe needles. The sensor probe is inside the needle. Once the sensor probe is inserted, the needle is pulled out and the sensor probe stays under your skin for up to 15 days. The sensor continuously measures your blood sugar levels every 15 minutes. You will be instructed on how to apply the device using a publically available

instruction video (https://www.stelo.com/guides), instruction handout (https://www.stelo.com/guides), and/or during a teleconference visit with the study Registered Dietitian ~4-5 days before you start the diet. The device is FDA approved for people not taking insulin and is not intended for the management or treatment of prediabetes or type 2 diabetes. This device will not be used to monitor any clinical symptoms associated with your prediabetes diagnosis (e.g., hypoglycemic/ hyperglycemic episodes). If you were to experience a clinical symptom, we are unable to provide medical advice based on your continuous glucose monitoring readings and instead we will ask that you seek medical attention or contact your healthcare provider to schedule a visit. You will be asked to adhere to the manufacture advice regarding abnormal readings (e.g., consulting with your healthcare provider if your readings are consistently outside the pre-set target ranges of 70-180 mg/dL).

Food checklists, food diaries, and the Daily Eats diet questionnaires will be provided to you in-person to complete at home. At the end of each week, you will send the completed documents to the study team. To do this, you will need to take a photo of the questionnaire with your phone and upload it to an application called MyCap app.

Parents and children in both the *Whole Foods Counseling* group and the *Whole Foods Healthy Eating* group will have their height, weight, and waist measured two times during the 14-week study. We will also ask questions about you and your family's:

- Dietary habits
- Physical activity levels
- Alcohol use
- Supplement use

You will also have access to our study website which will include links to publicly available online cooking videos (e.g., cooking techniques), budget-friendly recipes, menu planners, in-store and online grocery shopping lists, and tips (including for low-income families that utilize the USDA Thrifty Food Plan).

How we will get in touch with you during and after the study:
If you agree, our research staff will text, call, email, send MyCap messages, or send letters (in the mail) to you 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 continue to contact you in case we have another phase of this study or studies in the future that you and your family might be interested in. You can decide at that time if you are interested. If you agree to allow us to remain in contact with you, we may ask you to update your

phone numbers, your address, and your additional contacts (in case we are unable to reach you at your phone number or your address). If you agree to allow us to remain in contact with you, we may call or text you, send a MyCap message, or send you updates via mail or email. This is optional and you can mark your choice at the end of this form.

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 child will be compensated for your time and could receive up to $115 (control group) or $145 (intervention group) for completing all study requirements (up to $50.00 [control group] or $80.00 [intervention group] for completing weeks 1-8 requirements, up to $35.00 for completing weeks 9-12, including final visit, study requirements, and up to $30 for completing a family focus group session). 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.

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 in person requirements (e.g., baseline study visit, surveys/questionnaires, anthropometry collection, HbA1c testing, indirect calorimetry) **Total Possible Compensation: $0.00**	120-180 minutes
Study Phase 1 (Weeks 1 to 8)	$50 for completion of ALL (8 weeks) dietary information (e.g., food checklist/food diaries, via MyCap [baseline and weeks 1, 2, 4 & 8], Diet Feasibility/Acceptability Survey [Weeks 2 & 6], Daily EATs survey [weeks 1, 2, 4, & 8]) or $10 for each week of dietary information completed. INTERVENTION ONLY: $30 for completion of ALL stool collections, continuous glucose monitoring setup/collection or $15 for 1 stool collection and 1-2 continuous glucose monitoring collection **Total Possible Compensation:** **Control Group: $50.00** **Intervention Group: $80.00**	10 minutes per item/collection 10 minutes per item/collection

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Study Phase 2 (Weeks 9 to 12 including follow-up visit)	$10 for completion of dietary information (e.g., 3-day food diaries week 10, Diet Feasibility/Acceptability Survey week 12, Daily EATs survey week 10). $25 for completion of in-person requirements (e.g., follow-up study visit, surveys/questionnaires, anthropometry and HbA1c collection, indirect calorimetry) **Total Possible Compensation: $35**	10 minutes per item/collection 90-120 minutes per collection
Family Focus Groups	$30 (requires index parent with or without child/adolescent participation) **Total Possible Compensation: $30.00**	120-150 minutes

***participants must complete 3 weeks of activities during phase 1 and/or phase 2 to receive the minimum compensation ($25 minimum)**

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.).

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

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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?
You may stop being in (withdraw from) the Whole Food for Families 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 **615-343-9548.**

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.

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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 child, 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.

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 child's 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 health care 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.

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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.

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.

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.

PARTICIPANT:

Date	Signature of Patient/Volunteer
	Printed Name of Patient/Volunteer

CONSENT OBTAINED BY:

Date	Signature
	Printed Name and Title