Washington University in St. Louis

INFORMED CONSENT DOCUMENT

Project Title: Addressing Social Determinants of Health during Clinical Care Visits to Promote Equitable Behavior Change and PREVENT Cardiovascular Disease

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- If you are the parent/guardian of a child under the age of 18 who is being invited to participate in this study, the word "you" in this document refers to your child. As the parent/guardian, you will be asked to read and sign this document to give permission for your child to participate.
- If you are under the age of 18 and reading this document, the word "you" in this document refers to you. You will be asked to read and sign this document to indicate your willingness to participate.

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant.

- You should read and understand the information in this document including the procedures, risks and potential benefits.
- If you have questions about anything in this form, you should ask the research team for more information before you agree to participate.
- You may also wish to talk to your family or friends about your participation in this study.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because you are a patient at the Late Effects Clinic who is between the ages of 12 and 19 years and is considered at-risk for developing poor cardiovascular health. The purpose of this research study is to test the PREVENT tool to help providers address overweight and obesity among at-risk adolescents. The tool helps healthcare providers administer physical activity and nutrition goals to their patients and provide community resources that will support those goals. This study will examine whether your behaviors and health outcomes change and whether you find the tool helpful. This study will also allow us to understand how the tool is used by your provider.

The PREVENT tool is considered investigational, which means that it has not been approved by the U.S. Food and Drug Administration.

WHAT WILL HAPPEN DURING THIS STUDY?

If you agree to participate in this study, you will attend a routine clinic visit at the Late Effects Clinic. Prior to your clinic visit, you will complete a questionnaire and wear a physical activity tracking device (accelerometer) for one week. Additionally, our study staff will have access to your health data within your medical record to examine risk factors for cardiovascular health (height, weight, blood pressure, cholesterol, blood glucose, smoking status). You will then attend your clinic visit that will follow a normal clinic visit routine. During your clinic visit, the PREVENT tool may be used by your provider to help you achieve healthy behaviors. While your provider uses PREVENT, a member of our research team may observe and audio-record the interaction. Following the clinic visit, you will be sent brief questionnaires electronically or by mail immediately following your visit and at 4-, 8- and 12-weeks following the visit. Additionally, 12-weeks after the visit, you will be asked to re-wear the physical activity tracking device for one week. You may return to the clinic for a follow up visit after 12-weeks if it is part of your normal care plan advised by your provider. We will also contact a subset of patients and parents to conduct brief telephone interviews about your experiences with the PREVENT tool.

WILL YOU SAVE MY RESEARCH INFORMATION TO USE IN FUTURE STUDIES?

Your private information will NOT be used for future research studies or shared with other researchers for their studies, even if we remove identifiers.

Audio Recording/Video Recording/Photographs

One aspect of this study involves making audio recordings of you during your clinic visit. The audio-recording will capture your interaction with the person administering the PREVENT tool and will be used to understand how the tool is being delivered and any challenges with delivering the tool. Audio recordings are not mandatory for participation. If you would prefer not to be audio-recorded, please let us know and we will not record the clinic visit. Only the approved research team will have access to these audio recordings. Once these recordings are transcribed (i.e. typed out into text) and the study has ended, we will destroy them.

I give you permission to make audio recordings of me during this study.

_____Yes _____No
Initials Initials

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 50 people will take part in this study conducted by researchers at Washington University.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for:

- One visit (approximately 1 hour) with the Late Effects Clinic (in-person or via telemedicine)
- Baseline and Follow-up measurement delivered electronically or via the mail

- One brief (30-minute) phone interview
- Estimated total time of participation is 4-5 months

WHAT ARE THE RISKS OF THIS STUDY?

One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled *"How will you keep my information confidential?"* for more information.

WHAT ARE THE BENEFITS OF THIS STUDY?

You may or may not benefit from being in this study.

We hope that, in the future, other people might benefit from this study because based on the results from this study we hope to be able to use this tool in multiple clinics to prevent adolescents from developing poor cardiovascular health.

WHAT OTHER TREATMENT OPTIONS ARE THERE?

Instead of being in this study, you could receive routine care, which may or may not include recommendations for behavior change.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any additional costs for being in this research study.
You and/or your medical/hospital insurance provider will remain responsible for your regular medical care expenses.

WILL I BE PAID FOR PARTICIPATING?

You will be paid up to 100 dollars for being in this research study. You may receive $25 after baseline, $25 dollars after 3-month follow-up,$25 dollars for wearing an accelerometer device to measure your physical activity, and $25 for participating in a telephone interview. You will need to provide your social security number (SSN) in order for us to pay you. You may choose to participate without being paid if you do not wish to provide your social security number (SSN) for this purpose. You may also need to provide your address if a check will be mailed to you. We estimate that it will take between 2-4 weeks to receive your check. Your social security number is obtained for payment purposes only, it will not be retained for research purposes.

WHO IS FUNDING THIS STUDY?

The University and the research team are not receiving payment from other agencies, organizations, or companies to conduct this research study.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

Other people such as those indicated below may become aware of your participation in this study and

may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you. We will keep your participation in this research study confidential to the extent permitted by law.

- Government representatives (including the Office for Human Research Protections) to complete federal or state responsibilities.
- The U.S. Food and Drug Administration
- Your primary care physician if a medical condition that needs urgent attention is discovered.
- Hospital or University representatives to complete Hospital or University responsibilities.
- Information about your participation in this study may be documented in your health care records and will be available to anyone with access to your health care record, including your health insurance company. This information may also be released as part of a release of information request.
- The last four digits of your social security number may be used in hospital or University systems to track billing information for research procedures.
- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and the Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.
- Any report or article that we write will not include information that can directly identify you. The journals that publish these reports or articles require that we share your information that was collected for this study with others to make sure the results of this study are correct and help develop new ideas for research. Your information will be shared in a way that cannot directly identify you.

To help protect your confidentiality, we will collect only information needed to assess study outcomes, minimize to the fullest extent possible the collection of any information that could directly identify subjects, and maintain all study information in a secure manner. To help ensure participant privacy and confidentiality, only a unique study identifier (i.e. a series of numbers and letters rather than your name) will appear on the data collection form. Any collected patient identifying information corresponding to the unique study identifier will be maintained on a linkage file, store separately from the data. The linkage file will be kept secure, with access limited to designated study staff. Following data collection subject identifying information will be destroyed (within 3 years of the study closure), consistent with data validation and study design, producing an anonymous data set for analysis. Data access will be limited to study staff. Data and records will be kept locked and secured, with any computer data password protected. No reference to any individual participant will appear in reports, presentations, or publications that may come from the study.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

ARE THERE ADDITIONAL PROTECTIONS FOR MY HEALTH INFORMATION?

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, "How will you keep my information confidential?"

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your PHI for this research
- This authorization does not expire.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
    - To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ or you may request that the investigator send you a copy of the letter.
        - **If you revoke your authorization:**
            - The research team may only use and share information already collected for the study.
            - Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.
            - You will not be allowed to continue to participate in the study.

Can we contact you by email and/or text?

We would like to contact you by email and/or text for the purposes listed below. Some of these messages may contain health information that identifies you.

- Appointment scheduling.
- Delivery of a behavior change action plan developed during your clinic visit.
- Sending and following-up on electronic questionnaires and measurements.
- Follow-up to a question or adverse event.

Only the research team will have access to your email and/or text communications. We will only communicate in this method to send you the information listed above. If you have any questions, wish us to stop sending these messages or need to contact us for an urgent or emergent situation, please contact the research team member identified at the top of this document.

You should be aware that there are risks associated with sending your health information via email and/or text.

- Text messaging is not a secure communication method.
- There is always a risk that the message could be intercepted or sent to the wrong email address and/or phone number. To avoid this, we will send a test message to ensure we have the correct email address and/or telephone number.
- When using any computer you should be careful to protect your username and password. Make sure you log-out before getting up from the computer.
- If you share a home computer or cell phone with other family members, and do not want them to know you are participating in this study make sure you provide an email address or phone number that only you can access.
- Your employer will have access to any messages sent or received on any electronic devices used for work or through a work server.
- If you lose your phone, others may be able to access the messages that we send.

Do you agree to allow us to send your health information via email?

_____Yes **_____No**
Initials **Initials**

Do you agree to allow us to send your health information via text?

_____Yes **_____No**
Initials **Initials**

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed.

If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

WHAT IF I DECIDE TO WITHDRAW FROM THE STUDY?

You may withdraw by telling the study team you are no longer interested in participating in the study. If you decide to leave the study early, there are no consequences and no additional requirements.

Will I receive new information about the study while participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

Can someone else end my participation in this study?

Under certain circumstances, the researcher might decide to end your participation in this research study earlier than planned. This might happen for no reason or because in our judgement it would not be safe for you to continue, or because the funding for the research study has ended.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Maura Kepper, 314-953-0142. If you experience a research-related injury, please contact: Maura Kepper, 314-953-0142.

If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office 1-(800)-438-0445, or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, http://hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study. As a participant you have rights and responsibilities as described in this document and including:

- To be given enough time before signing below to weigh the risks and potential benefits and decide if you want to participate without any pressure from the research team or others.
- To understand all of the information included in the document, have your questions answered, and receive an explanation of anything you do not understand.
- To follow the procedures described in this document and the instructions of the research team to the best of your ability unless you choose to stop your participation in the research study.
- To give the research team accurate and complete information.
- To tell the research team promptly about any problems you have related to your participation, or if you are unable to continue and wish to stop participating in the research study.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed and dated copy of this form.

Do not sign this form if today's date is after EXPIRATION DATE: 10/05/21.

_____ _____
(Signature of Participant) (Date)

_____
(Participant's name – printed)

Parent/Guardian Name and Relationship to Participant:

Do not sign this form if today's date is after EXPIRATION DATE: 10/05/21.

_____
(Child's name – printed)

_____ _____
(Signature of Parent/Guardian) (Date)

_____ _____
(Name of Parent/Guardian- printed) (Relationship to participant – printed)

FOR IRB USE ONLY
IRB ID #: 202007026
APPROVAL DATE: 06/13/22
RELEASED DATE: 06/13/22
EXPIRATION DATE: 06/12/23

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that they understand the risks, benefits, and procedures involved with participation in this research study.

_____ _____

(Signature of Person who Obtained Consent) (Date)

_____

(Name of Person who Obtained Consent - printed)