

Official Title: Wake Forest NCORP Research Base - Assessing Effectiveness and Implementation of an EHR Tool to Assess Heart Health Among Survivors - Coordinating Center

NCT03935282

IRB Approval Date: 11/06/2019

Informed Consent Form to Participate in Research for **Survivor** Participant

Study Title for Study Participants: Automated Heart-Health Application for Survivors (AH-HA)

Official Study Title for Internet Search on <http://www.ClinicalTrials.gov>: Protocol WF-1804CD, Assessing Effectiveness and Implementation of an EHR Tool to Assess Heart Health among Survivors (NCT03935282)

Overview and Key Information

What am I being asked to do?

We are asking you to take part in a research study. This study has public funding from the National Cancer Institute (NCI), part of the National Institutes of Health (NIH) in the United States Department of Health and Human Services. We do research studies to try to answer questions about how to prevent, diagnose, and treat diseases like cancer, as well as to determine the effectiveness of cancer clinical procedures. We are asking you to take part in this research study because you have received treatment for breast, prostate, colorectal, endometrial, or Hodgkin and non-Hodgkin lymphoma cancer.

Taking part in this study is your choice.

You are receiving care at an oncology practice participating in a research study. You can choose to take part, or you can choose not to take part in the survey part of the study. You also can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

This document has important information to help you make your choice. Take time to read it. Talk to your doctor, family, or friends about the risks and benefits of taking part in the study. It's important that you have as much information as you need and that all your questions are answered. See the "Where can I get more information?" section for resources for more clinical trials and general cancer information.

Why is this study being done?

This study is being done to answer the following question: Does the AH-HA clinical decision support tool in the electronic health record (EHR) help healthcare providers manage patients' cardiovascular health after cancer treatment? The AH-HA tool is a visual display in the electronic health record that shows cardiovascular disease risk factors. This tool may help patients and providers make decisions about cardiovascular health.

What is the usual approach to my care?

The usual approach for patients who are not in a study is to get advice from their doctor without the use of the AH-HA tool. You are receiving care either at a site that provides usual follow-up care or at

a site that uses the AH-HA tool in addition to usual follow-up care. At all participating clinics, you will be provided with the usual follow-up care offered by the clinic for patients who have had a cancer diagnosis. Additional services may also be offered and will vary from clinic-to-clinic. These can include weight management with diet and physical activity recommendations, blood pressure and blood sugar control, and smoking cessation programs.

What are my choices if I decide not to take part in this study?

- You may choose to have the usual approach described above. You can still receive care at a clinic that is participating in the study even if you choose not to participate in the survey part of the study.
- You may choose to take part in a different research study, if one is available.

What will happen if I decide to take part in this study?

If you decide to take part in this study, you will be asked to complete 2 short surveys, less than 30 minutes total before and after your clinic visit. We also request your permission to obtain medical record information from this and other (primary care, cardiology) clinics and combine these results with the survey results. After your visit today, you will be asked to complete another short survey at 6 months and at 1 year from today. These surveys are estimated to take less than 15 minutes each.

What are the risks and benefits of taking part in this study?

There are both risks and benefits to taking part in this study. It is important for you to think carefully about these as you make your decision.

Risks

We want to make sure you know about a few key risks right now. We give you more information in the “What risks can I expect from taking part in this study?” section.

If you choose to take part in this study, there is a risk that:

- You may find discussing your cardiovascular health or other personal information with others to be uncomfortable, embarrassing, and/or stressful.
- You may be asked to provide information that you consider confidential or private.

There may be some risks that the study doctors do not yet know about.

Benefits

If you agree to take part in this study, there may or may not be direct benefit to you. You may receive information about heart health that may help you make medical or lifestyle decisions. We hope the information learned from this study will benefit other people in the future.

If I decide to take part in this study, can I stop later?

Yes, you can decide to stop taking part in the study at any time. If you decide to stop, let your study doctor know as soon as possible. If you stop, you can decide if you want to keep letting the study doctor know how you are doing.

Your study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

Are there other reasons why I might stop being in the study?

Yes. The study doctor may take you off the study if:

- Your health changes and the study is no longer in your best interest.
- New information becomes available and the study is no longer in your best interest.
- You do not follow the study rules.
- The study is stopped by the Institutional Review Board (IRB), Wake Forest NCORP Research Base, or study sponsor National Cancer Institute (NCI). The study sponsor is the organization who oversees the study.

It is important that you understand the information in the informed consent before making your decision. Please read, or have someone read to you, the rest of this document. If there is anything you don't understand, be sure to ask your study doctor or nurse.

What is the purpose of this study?

The purpose of this study is to examine the effects of a clinical decision support tool in the electronic health record. The clinic you are visiting is part of a randomized trial designed to test whether a clinical decision support tool improves their ability to manage patients' cardiovascular health. We are working with 12 clinics across the United States; half of the clinics will use the tool and half of the clinics will not use the tool. We are inviting you to participate in this study to help us evaluate the effectiveness of our tool. We expect to enroll 600 participants.

What are the study groups?

In this study, clinics are randomly assigned into two groups (similar to flipping a coin). One group of clinics will provide patients with their usual follow-up care services that are already routinely offered for all cancer survivors. Clinics in the other group will have access to the cardiovascular health tool, and oncology providers within these clinics will receive training on how to use the cardiovascular health tool with patients.

What exams, tests, and procedures are involved in this study?

Aside from surveys, there are no additional tests or procedures involved if you take part in this study.

If you are an English or Spanish speaker and choose to take part in this study, you will be asked to fill out a brief 15-minute survey about your general health and health behaviors, as well as your

impressions of your medical appointment. Researchers will use this information to determine the effectiveness of the AH-HA tool.

You will be asked to fill out a survey 4 times:

- Before your appointment today
- After your appointment today
- 6 months from today (at clinic appointment or by phone)
- 1 year from today (at clinic appointment or by phone)

Each survey will take about 15 minutes to complete. The survey will ask about things like exercise, nutrition, understanding heart health, and so on. You don't have to answer any question that makes you feel uncomfortable. Thus, you will be in this study for a total of one year. You can stop participating at any time. This clinic is committed to providing you with high quality of care regardless of whether you choose to participate.

You will also be asked to sign a medical release so that study staff can review your medical records from this oncology provider and other providers from whom you might receive care (e.g., primary care and cardiology).

What risks can I expect from taking part in this study?

Risks of this study include that some individuals may find discussing their cardiovascular health or other personal information with others to be uncomfortable and/or stressful. Every effort will be made, however, to address each participant's concerns or problems in the most supportive and empathic manner. Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe. A Data Safety and Monitoring Committee, an independent group of experts, will be reviewing the data from this research throughout the study. Although unlikely, there also may be other side effects that we cannot predict.

What are my responsibilities in this study?

If you choose to take part in this study, you will need to:

- Keep your study appointments and/or study phone calls.
- Tell your doctor about:
 - any doctors' visits or hospital stays outside of this study

What are the costs of taking part in this study?

There are no costs to you for taking part in this study. You and/or your insurance plan will need to pay for the costs of medical care you get during the study, just as you would if you were getting the usual care for your cancer follow-up appointments. This includes your insurance co-pays and deductibles for cancer follow-up appointments. Talk to your insurance provider to find out if you need approval from your plan before you can take part in the study.

The research may lead to new tests, drugs, or other products for sale. If it does, you will not get any payment. You will receive a gift card after completion of the surveys throughout this study as a thank you for your time. You will receive \$10 for today, \$5 at 6 months from today and \$5 at 1 year from today for a total of \$20.

What happens if I am injured because I took part in this study?

If you are injured because of taking part in this study and need medical treatment, please talk with your study doctor right away about your treatment options. The study sponsors will not pay for medical treatment for injury. Your insurance company may not be willing to pay for a study-related injury. Ask them if they will pay. If you do not have insurance, then you would need to pay for these medical costs.

If you feel this injury was caused by medical error on the part of the study doctors or others involved in the study, you have the legal right to seek payment, even though you are in a study. Agreeing to take part in this study does not mean you give up these rights.

Who will see my medical information?

Your privacy is very important to us. The study doctors will make every effort to protect it. The study doctors have a privacy permit to help protect your records if there is a court case. However, some of your medical information may be given out if required by law. If this should happen, the study doctors will do their best to make sure that any information that goes out to others will not identify who you are.

Some of your health information, such as your response to cancer treatment, results of study tests, and medicines you took, will be kept by the study sponsor in a central research database. However, your name and contact information will not be put in the database. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

There are organizations that may look at or receive copies of some of the information in your study records. Your health information in the research database also may be shared with these organizations. They must keep your information private, unless required by law to give it to another group.

Some of these organizations are:

- The study sponsor supporting the study now or in the future.
- The NCI Central IRB, which is a group of people who review the research with the goal of protecting the people who take part in the study.
- The NCI and the groups it works with to review research.
- Wake Forest NCORP Research Base or a representative working on its behalf
- The Study investigator and his/her staff

In addition to storing data in the study database, data from studies that are publicly funded may also be shared broadly for future research with protections for your privacy. The goal of this data sharing is to

make more research possible that may improve people's health. Your study records also will be stored for future use in public databases. However, your name and other personal information will not be used.

Some types of future research may include looking at your information and information from other patients to see who had side effects across many studies or comparing new study data with older study data. However, right now we don't know what research may be done in the future using your information.

This means that:

- You will not be asked if you agree to take part in the specific future research studies using your health information.
- You and your study doctor will not be told when or what type of research will be done.
- You will not get reports or other information about any research that is done using your information.

Where can I get more information?

You may visit the NCI Web site at <http://cancer.gov/> for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER (1-800-422-6237).

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.

You can talk to the study doctor about any questions or concerns you have about this study or to report side effects or injuries. Contact the study doctor (*insert name of study doctor[s]*) at (*insert telephone number, and email address if appropriate*).

For questions about your rights while in this study, call the (*insert name of organization or center*) Institutional Review Board at (*insert telephone number*).

My Signature Agreeing to Take Part in the Study

I have read this consent form, or had it read to me. I have discussed it with the study doctor and my questions have been answered. I will be given a signed and dated copy of this form. I agree to take part in the study.

Participant's signature _____

Date of signature _____ Time of signature: _____ AM/PM

Signature of person(s) conducting informed consent discussion _____

Date of signature _____ Time of signature: _____ AM/PM