Family History and Cancer Risk Study
NCT NCT05079334
IRB 201202
ICF
7/16/24

INSTITUTIONAL REVIEW BOARD
INFORMED CONSENT DOCUMENT FOR RESEARCH
MASTER CONSENT

Study Title: **FOREST (Family History and Cancer Risk Study)**
Version Date: **07/16/2024**

Part 1 of 2: MASTER CONSENT

Name of participant: _____ Age: _____

You are being invited to take part in a research study. This study is a multi-site study, meaning it will take place at several different locations. Because this is a multi-site study this consent form includes two parts. Part 1 of this consent form is the Master Consent and includes information that applies to all study sites. Part 2 of the consent form is the Study Site Information and includes information specific to the study site where you are being asked to enroll. Both parts together are the legal consent form and must be provided to you.

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:
The purpose of this study is to see if a family health history software tool (MeTree) is helpful in telling you and your doctor(s) about risks for future health conditions. The tool will ask you information about you and your immediate family, and the tool will give you a report with recommendations based on this information.

MeTree checks your risk for breast, colon, ovarian, and hereditary cancers (cancers that run in families), heart disease, and several other conditions (see the full list in location on Appendix A). Based on your risk, MeTree gives information to you and your doctors on how to improve your future health care and lower your risk for these conditions.

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 are:

- Receiving medical care at Vanderbilt University Medical Center or Meharry Medical College
- Age 18 years or older
- Able to read and communicate in English
- Willing to use the Internet
- Current My Health at Vanderbilt (MHAV) user or willing to sign up and use (Vanderbilt requirement only)

You do not have to be in this study. You may choose not to be in this study and it will not affect your healthcare, services, or other rights. You can stop being in this study at any time. We will tell you of any changes to risks in this study. If you choose to be in the study, your medical record will contain a note about the research study and your risk information. Anyone you allow to see your medical record will also get this information.

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Side effects and risks that you can expect if you take part in this study:
There are no physical risks associated with this study. There is, however, the potential risk of loss of confidentiality. All efforts, within reason, will be made to keep your research data private. Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions, and you may take a break at any time during the study. The recommendations from the report may cause concern or anxiety. At any point during the study, you have the opportunity to talk to study staff about your concerns. You may stop your participation in the study at any time by contacting the study team at:

Vanderbilt University Medical Center: (615)343-4991 or forest_team@vumc.org

Risks that are not known:
There may be additional risks of participating that are unknown at this time.

Good effects that might result from this study:
The benefits to science and humankind that might result from this study. If you agree to take part in this study, there may be direct medical advantages to you. This may include information about your risk for breast, colon, ovarian, and hereditary cancers and coronary heart disease and health behaviors (such as changes in physical activity or diet) and screening suggestions to lower your risk. You will receive a copy of your family health history pedigree and the results of your risk assessment. We hope that in the future the information learned from this study will advantage other people also.

Procedures to be followed:
You will read and digitally sign this consent form if you want to participate. After signing, you will complete a survey and we will provide a link to access MeTree, the family health history risk tool. You will be asked to enter your family health history on the computer. The survey will ask for information about your diet, exercise, medical history, and family health history.

A report with information about your risk and suggestions for ways to stay healthy will be created based on the information entered into the MeTree software tool. You can save this report to your computer. You may also ask to have a copy be mailed to you. A report will be sent to your doctor as well.

Some participants may be referred to a provider to discuss their results. If your site has a Genetic Counselor, you may be referred to one. If your site does not have a Genetic Counselor, you may be referred to your Primary Care Provider. You are not required to meet with a Genetic Counselor to be a part of the study. Genetic counseling, clinic visits, and/or testing will not be paid for by the study.

We may ask you to complete other surveys or interviews about your experience with the software, or if you made any changes based on the information from the report.

We may ask some participants to check whether family members would like to be in the study. If they agree, we will contact them directly to speak with them about the study. You and your family members can always say no. Your family will not be contacted without your permission.

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Reasons why the study doctor may take you out of this study:
You may choose to stop participating at any time. Please let the study team know if you would like to withdraw from the study.

What will happen if you decide to stop being in this study?
If you decide to stop being part of the study, you should tell your study doctor. Deciding to not be part of the study will not change your regular medical care in any way.

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.

Privacy:
Any information about you may be made available to others to use for research. To protect your privacy, we will not release your name.

Study Results:
A report with information about your risk and suggestions for ways to stay healthy will be created based on the information entered into the MeTree software tool. You can save this report to your computer. You may also ask to have a copy be mailed to you. A report will be sent to your doctor as well. The report will not be shared with anyone else.