Study Title: IMProving Care After Inherited Cancer Testing (IMPACT) Study **Version Date**: October 28th, 2022
Principal Investigator: Tuya Pal, MD, FACMG NCT04763915

Name of Participant: _____ **Age**:_____

The following is given to you to tell you about this research study. Please read this form with care and contact the study team with any questions you may have about this study. Your questions will be answered.

Key Information:
The first section of this document contains key points 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 the study team.

Key information about this study:
The purpose of this study is to evaluate factors associated with access to genetic risk assessment, counseling, and testing services. You do not have to agree to be in this research study. 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 you still want to be in this study. If you are a Vanderbilt patient, your medical record may 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.

If you agree to be in the study, you will be asked to complete a baseline survey. The survey may take about 45 minutes to complete. You will also be asked to complete an authorization for release of medical records. All materials can be completed online or on paper. The study team will review your survey answers and medical records, and, if you are eligible, may invite you to participate in the second part of the study.

About 5,000 people will take part in this study.

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 had genetic testing for inherited cancer or meet national criteria for genetic testing for inherited cancer. You do not have to be in this research study. 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 you still want to be in this study. If you are a Vanderbilt patient, your medical record may 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:
This part of the study involves the completion of a survey; therefore, the risk of injury or personal harm due to this study is very low. There is always the chance that some of your private information may be accidentally released. The study team will do everything possible to reduce these risks. All study staff have received required training on how to keep information private.

Risks that are not known:
There may be risks that we do not know about at this time.

Good effects that might result from this study:
- The benefits to science and humankind that might result from this study: We do not yet know if or how the information from this study will benefit individuals at risk for inherited cancers.
- The benefits you might get from being in this study: We cannot guarantee any direct benefits to you by participating in this study.

Procedures to be followed:
If you agree to be in the study, you will be asked to complete a baseline survey. The survey may take up to 45 minutes to complete. You will also be asked to complete an authorization for release of medical records. All materials can be completed online or on paper. The study team will review your survey answers and medical records, and, if you are eligible, may invite you to participate in the second part of the study.

Payments for your time spent taking part in this study or expenses:
You will be offered a $10 gift card for completion of the baseline survey and signing the authorization for release of medical records. If you do not wish to sign the authorization for release of medical records, you will still be offered a $10 gift card if you provide a copy of your genetic test report to the research team.

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 as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided **at Vanderbilt** to treat the injury. There are no plans for Vanderbilt to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

Who to call for any questions or in case you are injured:
If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact Tuya Pal, MD, FACMG at 615-875-2444. For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the VUMC Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Reasons why the study doctor may take you out of this study:
You may be taken out of the study if you request it. If you are taken out of the study for any other reason, you will be told why.

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.

Confidentiality:
If you agree to take part in this study, all information collected during the study will be kept strictly confidential. In accordance with federal law, we will keep the study records private by storing them in a locked area or on a password-protected computer. Your identifying information, such as your name and contact details, will be kept in a secure location so that only the study team can access it. When we use data collected in the study, the information that identifies you will not be used. Instead, we will give you a study identification number that no one else can use to identify you. Your name or other information that would allow someone outside the study to identify you will never be used in study publications or reports.

Your study record will be kept separately from your regular medical record, and insurers will not have access to your study records. If insurance companies, employers, or others obtain genetic information about you from this research, it has the potential to affect your insurability or employability. This is why we will do our best to ensure that privacy of all identifiable study records will be protected to the full extent provided by law.

Vanderbilt may share your information, without identifiers, to others or use it for other research projects not listed in this form. Vanderbilt, Dr. Pal, and her staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

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.

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.

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:
In general, we will not give you any individual results from the study. It is possible that we will discover information of medical importance that is unrelated to the purpose of this study. If we believe that the information is of urgent medical importance, we will share this information with you.

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 healthcare 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 below. 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.

Tuya Pal, MD, FACMG
1500 21st Ave. So., Suite 2810
Nashville, TN 37212

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.

CONSENT TO TAKE PART IN THIS STUDY

If you want to take part in this study, please complete the enclosed survey and sign the authorization for release of medical records. By completing the survey, you agree that you have read this consent form and agree to take part in this research study.

Please keep this consent form for your records.