Informed Consent Document for Research

This informed consent applies to adults.

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.

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 or not you still want to be in this study. Your medical record will contain a note saying you are in a research study. Anyone you authorize to receive your medical record will also get this note.

1. What is the purpose of this study?

You are being asked to take part in this research study because you or a member of your family have been diagnosed with cancer.

The purpose of this research project is to create a registry of people interested in participating in studies of the genetic causes of cancer. Such studies evaluate the roles of genetic and environmental risk factors in the development of tumors or related conditions. We hope that knowledge gained from these studies will lead to both the earlier detection and prevention of tumors.

Participation in the registry is a way to be part of a large group of people who are providing important information for research and to be kept informed of research advances in cancer genetics. Individuals who participate in the registry will have the option to receive results from the research and to be contacted if a new research study opens for which they are eligible based on the information they have provided to the registry.

There may be 5,000 people who take part in this study.

2. What will happen and how long will you be in the study?

You will be asked to complete a personal and family history questionnaire. The questions will be about your medical and cancer history, risk factors, and family history of cancer. You can take your time answering the questions. You may be contacted by a member of the study team to confirm or clarify the information you provide in the questionnaires.

We will ask for your permission to obtain your medical records from your physician(s) or from hospitals where you have been treated or had surgery for tumors, cancer, or other illnesses.

If you are not already planning to have genetic counseling, it may be recommended for you. This would allow you to discuss the chance that the cancer in your family could be inherited and what the results of cancer gene testing, if available, would mean for you and your family. There is usually a fee for genetic counseling that is not covered by this research study and is the responsibility of the individual.

Depending on your family history, you may be asked to give a blood sample (about one to two tablespoons once and possibly again as time passes, but no more often than every six months), saliva sample, and/or a urine sample for future research, and/or to give permission for leftover blood from lab testing and/or tissue from previous surgeries (if any) to be used for future research. Any use of such specimens would require approval by
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the Vanderbilt Institutional Review Board, but willingness to donate samples is not required for you to be in ICARE.

You may be asked to discuss the registry with your family members who may also decide to be part of the study.

You will be asked to complete a follow-up questionnaire every one to two years regarding any health changes in you and your family.

This study visit will take about 2-3 hours of your time.

May we contact you for other studies for which you may be eligible?
☐ Yes ☐ No

3. Costs to you if you take part in this study:

There is no cost to you for taking part in this study.

4. Side effects and risks that you can expect if you take part in this study:

Blood draw
Pain, redness, soreness, bruising, or infection may occur at the needle stick site. Rarely some people faint.

Questionnaire
Filling out the questionnaire may be boring or may take a long time.

Genetic Information
Personal genetic information often applies to other family members. For this and related research you may be asked to share information with your family members. You will be asked to provide certain information about the medical history of your family members, but no information that identifies them. Strong steps will be taken to keep this information private. Different family members may have different feelings about sharing this type of information for the purposes of research. You have the right to not provide information about your family for this research.

However, because this type of research relies on family information, it is possible that you may not be able to take part in the study if you are not able to provide certain information. The study doctors will inform you if this occurs.

Insurers do not have access to your research records, which are not part of your regular medical record. The study doctors will not release information which might identify you with this study to anyone without your written permission. If insurance companies, employers, or others obtained genetic information about you from this research, it has the potential to affect your insurability or employability. The privacy of all the study records will be protected to the full extent provided by law.

5. Risks that are not known:

There may be risks that we do not know about at this time.
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6. 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.

7. Good effects that might result from this study:

a) The benefits to science and humankind that might result from this study. This study may help to increase our overall knowledge of how cancer may be inherited and how to treat patients in the future.

b) The benefits you might get from being in this study. None.

8. Other treatments you could get if you decide not to be in this study:

This is not a treatment study. You may decide not to be in the study and nothing about your healthcare will change.

9. Payments for your time spent taking part in this study or expenses:

We will not pay you for the time you volunteer while being in this study. However, as a small token of appreciation, you may receive promotional items (with a value of less than $10) while you are in this study.

10. 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.

11. 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. At that time we will stop gathering information about you and your samples will be destroyed, however the data that is already part of the study will be kept.

12. 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 Anne Weidner at 615-875-2444. If you cannot reach the research staff, please contact the study doctor at 615-936-2660.

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 Vanderbilt University Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.
13. Clinical Trials Registry.

A description of this clinical trial will be available on 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.

14. Confidentiality:

Federal law says we must keep your study records private. We will keep the records of this study private by keeping them in a locked area or on a secure computer.

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.

15. Authorization to Use/Disclose Protected Health Information

All efforts, within reason, will be made to keep your protected health information (PHI) private. PHI is your health information that is, or has been gathered or kept by Vanderbilt as a result of your healthcare. This includes data gathered for research studies that can be traced back to you. Using or sharing ("disclosure") such data must follow federal privacy rules. By signing the consent for this study, you are agreeing ("authorization") to the uses and likely sharing of your PHI. If you decide to be in this research study, you are also agreeing to let the study team use and share your PHI as described below.

As part of the study, Dr. Pal and her study team may share the results of your study and/or non-study linked genetic results, as well as parts of your medical record, to the groups named below. These groups may include people from the Federal Government Office for Human Research Protections and the Vanderbilt University Institutional Review Board. Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your PHI private.

The study results will be kept in your research record for at least six years after the study is finished. At that time, the research data that has not been put in your medical record will be kept for an unknown length of time. Any research data that has been put into your medical record will be kept for an unknown length of time.

Unless told otherwise, your consent to use or share your PHI does not expire. If you change your mind, we ask that you contact Dr. Pal in writing and let her know that you withdraw your consent. Her mailing address is:

Dr. Tuya Pal
Vanderbilt Clinical and Translational Hereditary Cancer Program
Village at Vanderbilt
1500 21st Ave. So., Suite 2810
Nashville, TN 37212

At that time, we will stop getting any more data about you. But, the health data we stored before you withdrew your consent may still be used for reporting and research quality.
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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.

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.

Date
Consent obtained by:

Signature of patient/volunteer

Date
Signature

Printed Name and Title

Time
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Consent for Genetic Research

The purpose of this study is to look at genes (DNA) and how they affect health and disease. Genes are the instruction manual for your body. The genes you get from your parents decide what you look like and how your body behaves. They can also tell us a person’s risk for certain diseases and how they will respond to treatment.

You are being asked to give a blood, urine, saliva, tissue, and/or other biological sample for genetic research. What we learn about you from this sample will not be put in your health record. No one else (like a relative, boss, or insurance company) will be given your test results. Your sample will only be used for research at Vanderbilt University and will not be sold. Health insurance companies and group health plans may not request your genetic information that comes from this research.

A single blood sample of 2 tablespoons will be drawn from a vein in your arm using a needle and/or a cheek swab sample will be obtained and/or ask you for a urine sample. This will take not take any extra your time from the main study.

One risk of giving samples for this research may be the release of your name that could link you to the stored samples and/or the results of the tests run on your samples. This may cause problems with insurance or getting a job.

Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums. Employers with 15 or more employees may not use your genetic information that comes from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

To prevent this, these samples will be given a code. Only the study staff will know the code. The name that belongs to the code will be kept in a locked file or in a computer with a password. Only Dr. Pal and members of her study team will have access to your name.

Your sample will be used to make DNA that will be kept for an unknown length of time (maybe years) for future research. The sample will be destroyed when it is no longer needed.

Your samples may be used to make new products, tests or findings. These may have value and may be developed and owned by the study staff, Vanderbilt University, and/or others. If this happens, there are no plans to provide money to you.

Your samples and information about you may be shared with others to use for research. To protect your privacy, we will not release your name.

You will not receive any benefit as a result of the tests done on your samples. These tests may help us learn more about the causes, risks, treatments, or how to prevent this and other health problems.

At any time, you may ask to have your sample destroyed. You should contact:

Dr. Tuya Pal
Vanderbilt Clinical and Translational Hereditary Cancer Program
Village at Vanderbilt
1500 21st Ave. So., Suite 2810
Nashville, TN 37212
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...to have your sample destroyed and no longer used for research. We will not be able to destroy research data that has already been gathered using your sample. Also, if your identity was removed from the samples, we will not be able to locate and destroy them.

...There will be no costs to you for any of the tests done on your samples. You will not be paid for the use of your samples.

...Please check Yes or No to the questions below:

My blood/tissue sample may be stored/shared for future gene research in cancer.

☐ Yes ☐ No

My blood/tissue sample may be stored/shared for future gene research for other health problems (such as diabetes, heart disease, etc).

☐ Yes ☐ No

Signature: ___________________________ Date: ___________