Institutional Review Board
Informed Consent Document for Research

Principal Investigator: Tuya Pal, M.D. **Revision Date: 4/9/18**
Study Title: Inherited CAncer REgistry (ICARE) Initiative
Institution/Hospital: Vanderbilt University Medical Center

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.

1. What is the purpose of this study?

You are being asked to take part in this research study because you are interested in participating in studies focused on the genetic causes of 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 cancer.

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?

If you agree to be in the study, you will be asked to complete an initial questionnaire that will ask questions about your medical and cancer history, risk factors, and family history of cancer. You may also be asked to complete a follow-up questionnaire every one to two years regarding any health changes in you and your family. For all questionnaires, you can take your time answering the questions. You may be contacted by a member of the research team to confirm or clarify the information you provide in the questionnaires.

We will also ask for your permission to obtain your medical records from your healthcare provider(s), medical centers, or laboratories where you have received genetic counseling and/or testing or other medical care, including surgery for tumors, cancer, or other illnesses.

Genetic testing and counseling is not offered as part of this study. If you are not already planning to have genetic counseling, it may be recommended. Genetic counseling would allow you to discuss the chance that cancer in your family could be inherited and what 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.

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

This study in total is expected to take about 2-3 hours of your time. There is no travel required to participate in this study.

Through this study, you may be asked to give a blood sample, 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. Willingness to donate samples is not required for you to participate in ICARE.

A saliva sample may be collected using a saliva kit that can be mailed to your home. You may also be asked to provide a single blood sample of 2 tablespoons, which would be drawn from a vein in your arm using a needle.

What we learn about you from your sample(s) will not be put in your health record unless important health information is learned that may affect your care. No one else (like a relative, boss, or insurance company) will be given your test results. Your sample(s) will not be sold.

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. 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 filing cabinet or in a computer with a password. Only members of the research team will have access to your name.

Your samples may be kept for an unknown length of time (maybe years) for future research Your de-identified sample may be shared with research collaborators to contribute to future research. If additional results become available from testing your sample(s), you may be recontacted to determine if you would like to receive the results. 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 Medical Center, 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.

We cannot guarantee that you will personally 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:

The ICARE Study Team
Vanderbilt University Medical Center
1500 21st Ave. So., Suite 2810
Nashville, TN 37212

to have your sample(s) 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.

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
Genetic information about you often applies, to some degree, 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. You have the right to not provide information about your family for this research. We understand that family members may react differently towards sharing this type of information for the purposes of research.

Insurers do not have access to your research records, which are not part of your regular medical record. The study team will not release information that might identify you with this study to anyone without your written permission. The privacy of all the study records will be protected to the full extent provided by law.

A Federal law called the Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- 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 we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies, group health plans, and employers as outlined above must follow this law. Please note that this Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

5. Risks that are not known:

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

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 or at-risk individuals in the future.

b) The benefits you might get from being in this study: We cannot guarantee any direct benefits to you from participating in this study.

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?

Participation is fully voluntary. You can choose to stop being in this study at any time. If you decide to stop being part of the study, you should tell the research team or principal investigator. At that time, we will stop gathering information about you, however, the data that is already part of the study will be kept. If requested, any of your samples that have been collected will be destroyed.

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 the principal investigator Tuya Pal M.D. C/O the ICARE study team at 615-875-2444**.** If you cannot reach the research staff, please contact the principal investigator 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. Confidentiality:

If you agree to participate in this study, all information collected during the study will be kept strictly confidential. 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 password-protected computer. When we use data collected in this study, the information that

identifies you will not be used. Instead, you will be assigned a study identification number that no one else can use to identify you.

To help us protect your privacy, a Certificate of Confidentiality for this study has been obtained from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances: sexual or physical child abuse and/or the intent to hurt yourself or others. If any member of the program staff is given such information, they may report it to the appropriate authorities.

Vanderbilt, the principal investigator, and the research team will comply with any and all laws regarding the privacy of your information. There are no plans to pay you for the use or transfer of any of your de-identified information.

14. 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, Vanderbilt University Medical Center 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 destroyed. 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 the research team in writing to let them know that you withdraw your consent. The mailing address is:

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ICARE Study Team
Vanderbilt University Medical Center
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.

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.

One of the benefits of participating in this study is the ability to be informed of other studies you may be eligible to join. May we contact you for other studies for which you may be eligible?

☐ Yes ☐ No

Please check Yes or No to the questions below:

My biological sample(s) may be stored/shared for future gene research in cancer.

☐ Yes ☐ No

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

☐ Yes ☐ No

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

Date Signature of patient/volunteer

Consent obtained by:

Date Signature

Printed Name and Title Time

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COPY

Subject's Name_____

Subject's Medical Record # _____

Authorization for Release of Medical Records

Complete to request your medical records:

I,_____ born on _____/_____/_____hereby authorize:

First Name Middle Name Last Name

_____

Name of Institution(s):

_____

Address(es):

To please release and furnish to:

Dr. Tuya Pal
Vanderbilt Clinical and Translational Hereditary Cancer Program
Village at Vanderbilt
1500 21st Ave. So., Suite 2810
Nashville, TN 37212
Tel: 615-875-2444
Fax: 615-936-3648

The following medical information (*if applicable*) regarding hospitalization(s), care, and/or treatment as an inpatient, outpatient, or emergency department patient:

- Genetic test results
- Pedigree
- Surgical report
- Pathology report
- Chart summary
- Other relevant medical records

Purpose of Disclosure: Medical record review

I understand and acknowledge that this authorization extends to all or any part of the information designated above, which may include treatment for physical and mental illness, and/or alcohol/drug abuse, and/or AIDS (Acquired Immune Deficiency Syndrome), and/or may include the results of an HIV test or the fact that an HIV test was performed. Information in the form of audio, photo or video had been designated above if applicable. I expressly consent to the release of information designated above. This consent is valid for the duration of the study, unless revoked by my written notice, provided said notice is received prior to release of the above-designated information.

_____ _____

Signature of Patient Date

_____ _____ _____

Signature of person authorized to sign for patient Relationship to patient Date

Subject's Name_____

Subject's Medical Record # _____

COPY

Authorization for Release of Tissue/Tumor Specimens

Complete to request your tissue/tumor specimens:

I,_____born on_____/____/_____hereby authorize:
First Name Middle Name Last Name

_____

Name of Institution(s):

_____

Address(es):

Please release and furnish to:

Dr. Tuya Pal
Vanderbilt Clinical and Translational Hereditary Cancer Program
Village at Vanderbilt
1500 21st Ave. So., Suite 2810
Nashville, TN 37212
Tel: 615-875-2444
Fax: 615-936-3648

Tumor/tissue samples (*if applicable*) from surgery occurring as part of hospitalization(s), care, and/or treatment as an inpatient, outpatient, or emergency department patient.

Purpose of Disclosure: Histology and Pathology Review and/or Analyses

I understand and acknowledge that this authorization extends to all or any part of the information designated above, which may include treatment for physical and mental illness, and/or alcohol/drug abuse, and/or AIDS (Acquired Immune-Deficiency Syndrome), and/or may include the results of an HIV test or the fact that an HIV test was performed. Information in the form of audio, photo or video had been designated above if applicable. I expressly consent to the release of information designated above. This consent is valid for the duration of the study, unless revoked by my written notice, provided said notice is received prior to release of the above-designated information.

_____ _____
Signature of Patient Date

_____ _____ _____
Signature of person authorized to sign for patient Relationship to patient Date