INFORMED CONSENT FOR CLINICAL RESEARCH

Ascertainment of Peripheral Blood or Saliva Samples for Genetic Epidemiology Studies of Familial Cancers

You have been asked to participate in a research study. In order to decide whether or not you should agree to be part of this research study, you should know enough about its risks and benefits in order to make a sound judgment. This process is known as informed consent.

A member of the study staff will explain the research study to you. Research studies include only people who choose to take part. Please take your time to make your decision about taking part. You may discuss your decision with your family and friends.

This consent form gives you detailed information about the research study. Once you understand the study, its risks, and its benefits, you will be asked to sign the form if you wish to take part. You will be given a copy to keep.

Why is this study being done?

The purpose of this study is to better understand the genetic causes of cancer and the inherited tendency to develop cancer. To accomplish this, blood specimens and/or saliva samples and/or tumor and normal tissue blocks from patients and families of patients with cancer will be collected. Blood specimens will be frozen and stored for analysis at a later date. Tumor tissue and normal tissue will be stored for analysis at a later date. In order to perform this study, patients and members of their families will be asked to provide blood samples and/or saliva samples. Individuals will be asked to provide a history of cancer in their relatives at the time the blood sample is given. No relatives will be contacted before they have been asked by a family member if they wish to participate in this study. If they do wish to participate, the relatives should indicate this by returning the "Family Member Consent for Contact Form" (Appendix B). After we receive this form, arrangements may be made for the family member to send in a blood and/or saliva sample or to come in person to provide the sample to us.

Except for family history, no medical information provided by one member of a family will be discussed with other family members. At the end of this form, we will also ask for your permission to be contacted in the future to discuss information about your health, additional research with your samples and/or certain research findings possibly related to your sample.

Patients and their families will be offered referral for genetic counseling regarding their risk for cancer and the options for medical care given that risk. Should this research program result in a more accurate determination of the risk based on analysis of the blood and/or saliva sample, following New York State Department of Public Health approval, genetic test results, and counseling will be offered to explain that risk.

Is there a potential conflict of interest for this study?

There are no known investigator and/or institutional conflicts of interest for this study.

How was I selected to be in this study?

You are being asked to take part in this study because of your personal and/or family history of cancer. Patients may also be selected by consenting to participate in the study through a family member who is already enrolled.

How many people will take part in the study?

There is no fixed requirement for this study.

What will happen if I take part in this research study?

This study involves the drawing of blood from a vein and/or a saliva sample so that genetic material can be studied at a later date. Three tubes of blood, approximately 30 milliliters, will be drawn and/or 2 ml of your saliva may also be collected. This should take only a few minutes. As part of this process, you will be asked information regarding your family history of cancer. This interview, which may take place in person or on the phone, will take approximately 20 minutes. You will be asked if you wish to receive, or not receive, results of this research.

It is possible that in the future, blood tests will provide a basis for new cancer therapies, earlier diagnosis or identification of individuals at special risk for cancer. In order for these studies to potentially be of benefit to you or your family, genetic material from several relatives in multiple generations must be available. The sample(s) may also be used to detect new genes or changes in genes that may tell us who is at risk for certain types of cancer and/or other diseases. Should these studies allow a better estimation of your risk for cancer, we would need to seek approval by the New York State Department of Health in order to share research results with you. Following that approval you and your family will be offered counseling regarding that risk and your options for medical care.

The study may also involve the procurement of tumor and normal tissue. If you have had cancer, you may be asked to sign a release form that will allow us to obtain your blocks or slides and corresponding pathology reports from the hospital where the procedure was performed. If your surgery was performed at Memorial Sloan-Kettering Cancer Center, your signature on this consent will serve as the release.

Should you elect not to know the results of this study we will honor your request. However, if relevant information concerning your health becomes available many years from now we will contact you and give you the opportunity to decide whether you would at that time be interested in discussing the findings. If you elect not to know the results at that time we will honor your wishes. Whether you presently decide to be contacted in the future or not, it is very important that you notify us of any change of address.

Before you begin the study …

- You will be asked information regarding your personal and family history of cancer.
- If you are not an MSKCC patient at the time when you are approached for the study then you will be asked for demographic and personal information to enroll you onto the study.

During the study…

During the study you will not be contacted again unless relevant information concerning your health or your relatives' health is needed.

After the study…
. You will not be contacted again unless relevant information concerning your health becomes available. At that time, we will contact you and give you the opportunity to decide whether you would be interested in discussing these findings.

How long will I be in the study?

This study involves a one time donation of blood and/or saliva. The blood, saliva, and tissue specimens obtained for this research will be the exclusive property of Memorial Sloan-Kettering Cancer Center. The Center may retain, preserve, or dispose of these specimens and may use these specimens for research which may result in commercial uses. You will not receive money for any future commercial applications of this research project.

Can I stop being in the study?
Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop.

The study doctor may stop you from taking part in this study at any time if he/she believes it is in your best interest; if you do not follow the study rules; or if the study is stopped.

What side effects or risks can I expect from being in the study?

Side effects of this study include a small risk for bleeding or bruising associated with the drawing of blood. These side effects rarely pose a significant medical problem. If you are injured as a result of your participation in this research study, emergency care, hospitalization and outpatient care will be made available by the hospital and billed to you as part of your medical expenses. No money will be provided by the hospital as compensation for a research-related injury.

If in the future, this study results in information regarding your risk for cancer, and you should choose to be informed of this information, it is possible you will experience emotional distress. For this and other reasons, access to genetic counseling will be made available to you and members of your family.

Although laws exist to prevent abuses made possible by access to genetic information, genetic testing can lead to discrimination. Future genetic analysis of stored blood or saliva samples could theoretically compromise your ability to obtain insurance at that time. To minimize the possibility of genetic discrimination, all data will be kept in a confidential and coded manner, separate from your hospital record.

Are there benefits to taking part in the study?

Although we hope that this research study will be of benefit to you and that it will help others, we cannot say that this will help you directly. There are no plans for you to receive any payment for giving a sample as part of this study. There are also no plans for you to receive money for any new products, tests, or discoveries that might come from this research.

Will I receive the results from the study?

We will not be able to tell you any specific results of this research testing nor will we put the results in your medical record.

With your permission, we may contact you in the future about our research findings, but not your specific results. At times, MSKCC will announce our research findings to the general public. This information is often provided to the public in published articles and available for you and your family to read.

Should you elect not to know the results of this study we will honor your request. However, if relevant information concerning your health becomes available many years from now we will contact you and give you the opportunity to decide whether you would at that time be interested in discussing the findings. If you elect not to know the results at that time we will honor your wishes. Whether you presently decide to be contacted in the future or not, it is very important that you notify us of any change of address.

If you and/or your family have questions about our research discoveries and how they may benefit you or your family in relation to choices regarding preventive or clinical care, you will be referred to our Clinical Genetics Service and/or a member of your treatment team.

Do I have to take part in this study?

The choice to take part in this study or not is yours. Make your choice based on what we have explained to you and what you have read about the study. If you decide not to participate, other choices are available to you without prejudice. If you begin the study, you still have the right to withdraw at any time.

Will my medical information be kept private?

Every effort will be made to keep your study records private. It is the responsibility of the research staff at Memorial Hospital to make sure that your records are managed to protect your privacy. If information from this study is used in any reports or publications, your name and anything else that could identify you will not be used. Trained staff at Memorial Hospital may review your records if necessary. Access to your medical information will be limited to those listed in the Research Authorization Form, which is a part of the informed consent process.

It is possible that information from analyses of your samples and your medical information will be shared with other investigators or put into an access controlled online database. Only researchers who have received approval from a National Institutes of Health Data Access Committee will be allowed to access the online database. This database will not contain any identifying information about you, such as your name, address, telephone number, or social

security number. Your personal identifying information will not be shared with other investigators. Your privacy is very important to us and we use many safety procedures to protect your privacy. However, we cannot guarantee that no one will ever been able to use your genetic information to identify you.

A description of this clinical trial may be available on http://www.ClinicalTrials.gov. 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.

What are the costs of taking part in this study?

There will be no cost charged to you for blood sampling. However, if your blood is drawn outside of Memorial Hospital you may receive a bill for the procedure. You will be responsible for that bill.

There will be no cost for genetic counseling related to the signing of this informed consent, participation in this research study, or notification of research DNA results. Should you elect to receive more extensive genetic counseling relating to cancer prevention and screening options, or individualized risk assessment based on laboratory tests which are commercially available, you will be responsible for the costs of that consultation.

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

You will get medical treatment if you are injured as a result of taking part in this study. You and/or your health plan will be charged for this treatment. The study will not pay for the medical treatment.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

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

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Who can answer my questions about the study?

You can talk to your study doctor about any questions or concerns you have about this study. Contact your study doctor Dr. Kenneth Offit at (212) 434-5149 .

Any hospital that does research on people has an institutional review board (IRB). This board reviews all new studies to make sure that the patient's rights and welfare are protected. The IRB at MSKCC has reviewed this study.

For a non-physician whom you may call for more information about the consent process, research patients' rights, or research related injury is Jorge Capote, RN, Patient Representative, telephone number: (212) 639-8254.

Optional: Participation by other relatives and future studies

Please read each sentence that follows and think about your choice. After reading each sentence, circle "yes" or "no" and write your initials in the space provided. If you have questions, please contact a research study staff member. Remember, no matter what you decide to do about the following options, you may still take part in this study.

By circling yes or no, you understand and agree that:

1. You agree to contact your brother(s) and/or sister(s) for possible participation in this study. If you agree, we will request that you make the initial contact with your relative(s) about participating in this study.

   YES NO

2. MSKCC may contact me in the future to see if I might be interested in taking part in other genetic research studies.

   YES NO

Question/Answer for Future Use

By signing the consent to this study, you give permission for your sample to be kept for use in research to learn about, prevent, or treat cancer. The specimen will be used for research about inherited genetic factors that cause cancer.

By circling yes or no, you understand and agree that:

1. My sample may be kept for use in research to learn about, prevent, or treat other health problems (for example: diabetes, Alzheimer's disease, or heart disease)

   YES NO

2. Someone may contact me in the future to ask me for more samples to be collected for biospecimen research purposes or for information about my health.

   YES NO

3. Someone may contact me in the future to discuss findings which may come from my sample.

   YES NO

4. If unavailable, you give permission to discuss research findings with a family member.

   YES NO

Designated family member:

Name: _____

Address: _____

_____

Phone: _____

Relationship _____

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RESEARCH AUTHORIZATION

Information about you and your health is personal. It is "Protected Health Information." We cannot use any of your health information for research unless you tell us that we can. If you take part in this research, the people or organizations that can look at your information are listed below. You will have to sign this form to tell us we have your permission to share your protected health information.

The following persons and/or organizations may use or disclose your information for purposes related to this research:

- Members of the research team, including participating investigators, research assistants, clinical nurses, fellows/ residents, and clerical support staff.

The following persons and/or organizations may look at your information for purposes related to this research:

- Members and staff of the hospital's Office of Clinical Research, Computing Research Group that manages research databases, Data Safety Monitoring Board, and the Quality Assurance Committee.
- Members and staff of the hospital's Institutional Review Board and Privacy Board.
- The National Cancer Institute, National Institutes of Health, U.S. Food and Drug Administration, and other agencies responsible for oversight.
- Principal Investigator of this study: Kenneth Offit, MD, MPH
- The following sponsor(s) of this research: Memorial Sloan-Kettering Cancer Center
- Other: Foreign health regulatory agencies

The following information will be used and/or disclosed for this research:

- ☑ Your entire research record.
- ☑ HIV-related information. This includes any information showing that you had an HIV-related test, have HIV infection, HIV-related illnesses or AIDS, or any information that could mean you might have been exposed to HIV. New York State requires us to obtain this consent.
- ☑ HIV-related information collected during this study if you choose to disclose it when
- ☑ HIV talking to any of the staff.
- ☑ Your medical records from the hospital
- ☑ The following information:
  - Blood or saliva samples
  - Clinical Genetics notes, i.e. personal and family history of cancer

SPECIFIC UNDERSTANDINGS

If you sign this form, it means you are giving us permission to share your protected health information. We can only share it with the people or organizations describe above. The purpose for the use and sharing of this information is to conduct this study. This signed form allows us to make sure that everyone who needs information related to this study can get it.

Your protected health information may also be used for your research treatment, to collect payment for care you receive while on the study (when applicable), and to run the business operations of the hospital.

Some of the people or organizations listed above may not be subject to privacy laws. This means they could share your information again.

You do not have to sign this form. If you do not sign it, you will not be able to take part in the study. Your health care outside the study will not be affected. The payment for your health care or your health benefits will not be affected.

You have the right to withdraw from the study at any time. If you sign this authorization form, you also the right to withdraw it at any time. If you withdraw it, we cannot use or share anymore of your research data. If the hospital has already used or shared your information, it cannot be taken back. This authorization allows us to use your information until you say we cannot use it anymore. If you want to withdraw your authorization, write to: Dr. Kenneth Offit at the Department of Clinical Genetics Service Memorial Sloan-Kettering Cancer Center.

Notice About HIV-Related Information

Once we have shared your HIV-related information, it can only be shared again if federal or state laws allow it. You have the right to ask for a list of any people who get your HIV-related information that are not listed above. There are two agencies to help protect your rights. Call them if you think you have been singled out or harmed because of HIV-related information.

- New York State Division of Human Rights (800) 523-2437 or (212) 480-2493
- New York City Commission of Human Rights (212) 306-7450 or (212) 306-7500

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Statement of professional obtaining consent

I have fully explained this clinical research study to the participant or his/her Legally Authorized Representative (**LAR**). In my judgment and the participant's or that of his/her Legally Authorized Representative, there was sufficient access to information, including risks and benefits to make an informed decision.

Consenting Professional Must Personally Sign & Date		
Assent (Minor between the ages of 7 and less than 18): If the participant is a minor, I have obtained his/her assent to participate in the study to the best of their ability to understand. ☐ **YES** ☐ **NO** ☐ **N/A (Adult or Child <7)**		
Consenting Professional's Signature		**Date:**
Consenting Professional's Name (Print)		

Participant's (or Legally Authorized Representative's (LAR)) statement

I have read this form with the description of the clinical research study. I have also talked it over with the consenting professional to my satisfaction. By signing below, I am agreeing to the following: (1) to voluntarily be a participant in this clinical research study (2) authorizing for the use and disclosure of my/their protected health information (data about myself) and (3) that I received a signed copy of this consent form.

Participant/LAR Must Personally Sign & Date		
Participant/LAR Signature		**Date:**
Participant/LAR Name (Print)		
LAR Relationship to Participant		

Witness Signature (If Required)

☐ **Non-English Speaking Participant Witness and/or Interpreter:** I declare that I am fluent in both English and participant's (or LAR) language and confirm that the consent discussion was appropriately translated for the participant (or LAR).

☐ **Other:** I confirm that the consent discussion was appropriate for the participant's (or LAR's) understanding of the study.

Name of Witness: _____

Signature of Witness: _____ Date: _____

The Participant/Legally Authorized Representative Must Be Provided With A Signed Copy Of This Form.