PARTICIPANT INFORMED CONSENT FOR CLINICAL RESEARCH

Study Title for Study Participants: *Interest and Impact of Skin Cancer Genetic Testing*

Official Study Title for Internet Search on http://www.ClinicalTrials.gov:
Personalized Genomic Testing for Melanoma: Maximizing Comprehension and Health Outcomes in Skin Cancer Patients

Introduction

You have been asked to participate in a research study. A clinical trial is a type of research study. Clinical trials include only people who choose to take part. This consent form gives you information about the clinical trial and what it would involve if you take part. Members of the study team will discuss this information with you.

Please take your time to make a decision about whether to take part. You may discuss your decision with your family and friends. If you have any questions, you should ask your study doctor or your health care team for more explanation.

What are my other choices if I do not take part in this study?

If you decide not to take part in this study, you have other choices. For example:

- you may choose to take part in a different study, if one is available
- you may choose not to have a skin cancer genetic test done
- you may choose to pay for genetic testing from a company

Why is this study being done?

Scientists and doctors are learning more and more about why some people get skin cancer and others do not. Part of the reason involves genes. Genes carry the instructions that our bodies need to develop and function. Genes are passed down through family members. Most people have a large number of gene changes, known as "variants." Some (but not all) of these genetic variants are linked to increased risks of skin cancer, particularly a severe form of skin cancer called melanoma. Scientists have found that individuals who have a „risk version" of the MC1R gene are more likely to develop melanoma. People can have one or more risk versions of MC1R.

The purpose of this study is to learn whether you might be interested in skin cancer genetic testing, and if so, what kinds of thoughts, feelings, and behaviors might result from this testing if you decide to have it. Testing for skin cancer risk based on the MC1R gene is not currently used in clinical practice; it will be offered in this study for research purposes only.

About 75 people will take part in this study at Memorial Sloan Kettering Cancer Center (MSKCC).

What are the study groups?

There is only one study group for this study. All 75 participants will have a diagnosis of non-melanoma skin cancers. They will be offered the same skin cancer genetic test that you are offered. You do *not* have to agree to have the test in order to participate.

How long will I be in this study?

You will be asked to take part in this study for about six months.

What extra tests and procedures will I have if I take part in this study?

Most of the exams, tests, and procedures you will have are part of the usual approach for your cancer. However, there is an extra genetic test that you may request if you take part in this study.

Before you begin the study:

- There are no additional tests required for you to take in order to participate in this study.
- Your medical record will be reviewed by the research staff to determine your eligibility for participating in this study.
- We will also describe the study to you and answer any questions you may have.
- You will need to sign this consent form in order to participate in this study.

During the study:

If you choose to take part, you will then be asked to:

- Meet with one of our study staff at your clinic appointment and complete a survey that takes about 30 minutes. This survey asks about your thoughts, feelings and behaviors related to skin cancer prevention, information seeking, and demographic factors.
- After you complete the survey, our staff will give you an invitation to a website where you can read about skin cancer genetic testing. We have divided the website into 4 sections. The first 3 sections will teach you about genetic testing and skin cancer. We ask you to complete a brief survey in each of these 3 sections. Once you read these 3 sections and complete the surveys, you will be able to go to the 4th section where you will be able to request a skin cancer genetic test for yourself. You can decide to undergo testing or not. You will have about a month to decide whether you want the test done or not.
    - If you decide to undergo testing, we will mail you a kit to provide a saliva sample that you will be asked to mail back to the study staff. Postage costs will be provided. If the saliva sample is insufficient for testing, we will contact you to ask that you provide a new sample. We will use your sample(s) to examine your DNA and determine versions of the MC1R gene; however, this test cannot tell if you will definitely get melanoma.
    - Your saliva sample will be used to make DNA and will only be used for the testing

that is requested. It is likely that DNA will remain after the testing is done. By law, the laboratory retains the remaining DNA for 60 days. After this time, the laboratory will erase all identifiers on the sample that link it to you. The testing lab may use DNA sample(s) from you for research after we remove these identifiers, but no information specific to you will be obtained. Removing these links means that additional testing on you will require a new sample from you.

- Once the testing is complete, we will mail you a report that tells you whether you are at *average* or *above average* risk for developing melanoma skin cancer. You may want to consider further independent testing, consult your physician, or pursue genetic counseling.

- Two weeks after you receive your results, we will contact you by telephone to complete a 10-minute survey concerning your responses to the test report, and to answer any questions you may have.

- Finally, we will contact you (whether you received skin cancer genetic testing or not) by telephone about three months after your initial survey to complete a final survey concerning your thoughts, feelings, and behaviors regarding skin cancer and prevention. This survey will take about 20 minutes to complete.

What possible risks can I expect from taking part in this study?

If you choose to take part in this study, there is a risk that:

- You may lose time at work or home and spend more time in the hospital or doctor"s office than usual
- You may be asked sensitive or private questions which you normally do not discuss
- *There is a risk someone could get access to the personal information in your medical records or other information researchers have kept about you. Someone might be able to trace this information back to you. The researchers believe the chance that someone will identify you is very small, but the risk may change in the future as people come up with new ways of tracing information. In some cases, this information could be used to make it harder for you to get or keep a job. There are laws against misuse of genetic information, but they may not give full protection. The researchers believe the chance these things will happen is very small, but cannot promise that they will not occur.*
- *There can also be a risk in finding out new genetic information about you. New health information about inherited traits that might affect you or your blood relatives could be found during a study.*

Here are important points about side effects:

- The study doctors do not know who will or will not have side effects.

We do not expect physical injuries if you participate in this study.

Risks of genetic testing: If you do have a gene change that increases the chance of getting cancer and/or other diseases, there are some risks from learning this. These include psychologic or

emotional distress, loss of employment, or loss of insurance. Your family members could become upset to learn that they could be at increased risk, or that they may need increased screening or preventative surgeries. If at any point prior to, during, or after participation in this study, you want to talk about inherited risk factors that may increase you or your family members‟ risk of cancer and/or other diseases, we will refer you to a genetic counselor.

The US and some states have laws that forbid using your genetic information as a reason to fire you or not to give you a job. Under these laws, genetic information cannot be used to deny you health insurance or to raise the cost of your current health insurance, However, we cannot fully guarantee that no one will ever use your test results against you, and these laws do not apply to life or disability insurance, or if you are a member of the military.

Let your study doctor know of any questions you have about possible side effects. You can ask the study doctor questions about side effects at any time.

Is there a potential conflict of interest for this study?

The study is sponsored by Memorial Sloan Kettering Cancer Center. There are no known investigator and/or institutional conflicts of interest for this study

What possible benefits can I expect from taking part in this study?

We hope that the results from this study will help others in the future, although they will not help you directly now. You may learn new information about your risks for skin cancer and/or other diseases. You may or may not find this information helpful.

Can I stop taking part in this study?

Yes. You can decide to stop at any time. If you decide to stop for any reason, it is important to let the study doctor know as soon as possible so you can stop safely. If you stop, you can decide whether or not to let the study doctor continue to provide your medical information to the organization running the study.

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

The study doctor may take you out of the study:

- If your health changes and the study is no longer in your best interest
- If new information becomes available
- If you do not follow the study rules
- If the study is stopped by the sponsor, IRB or FDA.

What are my rights in this study?

Taking part in this study is your choice. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

For questions about your rights while in this study, call the Memorial Sloan Kettering Cancer Center Institutional Review Board at 212-639-7592. 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.

What are the costs of taking part in this study?

The genetic test and saliva collection kit will be supplied at no charge if you take part in this study.

There is no cost for taking part in this study.

If you agree to participate in this research, we will give you a $25 compensation for the initial survey you complete. For each survey on the website that you complete, we will mail you a $5 compensation for a total of $15 compensation. If you complete the genetic test and the survey asking for your feedback about the test report, we will mail you a $20 compensation. And finally, if you complete the survey 3 months following your initial participation, we will mail you a $20 compensation.

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

You will get medical treatment if you are injured as a result of taking part in the study.
If you think you have been injured as a result of taking part in this research study, you must tell your study doctor or the person in charge of this research study as soon as possible. The name and phone number of the person in charge of this research are listed on this consent form.

Jennifer L. Hay, PhD, 646-888-0039
Irene Orlow, PhD. 212-639-3072

If you feel this injury was a result of medical error, you keep all your legal rights to receive payment for this even though you are in a study.

Who will see my protected health information?

Your privacy is very important to us and the researchers will make every effort to protect it. Trained staff at Memorial Hospital may review your records if necessary.

If your information from this study is used in any reports or publications, your name or anything else that could identify you will not be used.

Your information may be given out if required by law. For example, certain states require doctors to report to health boards if they find a disease like tuberculosis. However, the researchers will do their best to make sure that any information that is released will not identify you.

Access to your protected health information will be limited to those listed in the Research Authorization form, which is a part of the informed consent process.

Where can I get more information?

You may visit the NCI Web site at http://cancer.gov/ for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER (1-800-422-6237).

A description of this clinical trial will be available on http://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.

Who can answer my questions about this study?

You can talk to the study doctor about any questions or concerns you have about this study or to report side effects or injuries. Contact the study doctor Jennifer Hay, PhD at 646-888-0039.

RESEARCH AUTHORIZATION FOR THE USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION

Interest and Impact of Skin Cancer Genetic Testing

Federal law requires Memorial Sloan Kettering (MSK) to protect the privacy of information that identifies you and relates to your past, present, and future medical conditions ("protected health information"). We are committed to protecting the privacy of your information.

If you enroll in this research study, your protected health information will be used and shared with others as explained below. MSK must obtain your permission before using or disclosing your protected health information for research purposes. This form helps make sure that you are informed of how your information will be used or disclosed in the future. Please read the information below carefully before signing this form. By signing this form, you agree to the use and disclosure of your information for this research study.

1. What protected health information about me will be used or shared with others during this research?

- Existing medical records
- Your research records which includes new health information created from study-related tests, procedures, visits, and/or questionnaires
- Biospecimens which includes things like tissue and blood. These will only be shared if you have agreed to this in the informed consent.
- HIV-related information. This includes any information indicating that you have had an HIV-related test, or have HIV infection, HIV-related illness or AIDS, or any information which could indicate that you have been potentially exposed to HIV. (New York State requires us to obtain special consent)

2. Who will use or share protected health information about me?

- MSK will use and share your protected health information. Individuals and offices that deal with research oversight, quality assurance and/or billing will be able to use and share your protected health information. These include
    - The study‟s Principal Investigator and Co-Principal Investigator(s): Jennifer Hay; Irene Orlow
    - Your research team at MSK including the participating investigators, research staff, research nurses, fellows/residents, and clerical support staff
    - Any health care personnel who provides services to you in connection with this study
    - The members and staff of the MSK‟s Institutional Review Board and Privacy Board
    - Staff of MSK‟s Office of Clinical Research which oversees clinical research and the Computing Resource Group who manage research databases
    - Members of the MSK‟s Data Safety Monitoring Board/Committee and Quality Assurance Committee

3. With whom outside of MSK may my protected health information be shared?

While all reasonable efforts will be made to protect the confidentiality of your protected health information, it may also be shared with the following:

- MSK‟s business partners, subcontractors and agent(s) working with MSK to conduct the study, to analyze the study information, or to monitor the study
- Federal and state agencies and other domestic or foreign government bodies if required by law and/or necessary for oversight purposes. These include:
    - Office of Human Research Protection (OHRP)
    - Department of Health and Human Services,
    - Food and Drug Administration and other regulatory agencies responsible for oversight.
    - National Cancer Institute (NCI)/National Institute of Health (NIH)

Some of these organizations who may receive your protected health information may not have to satisfy the privacy rules and requirements. They, in fact, may share your information with others without your permission.

4. Why will protected information about me be used by or shared by MSK or others?

The main reasons may include the following:

- To conduct the study, to monitor your health status, to measure the effects of drugs/device/procedures being studied and determine the research results
- To ensure the research meets legal and institutional requirements
- It may be used to develop new tests, procedures and commercial products
- Your study information may be added to research databases so that it can design better research studies in the future, develop other therapies for patients or gain a better understanding of disease

- For MSK medical treatment, billing matters, or health care operations. For example, medical information produced by this research study will become part of your hospital medical record.

5. For how long will protected health information about me be used or shared with others?

- There is no set date at which your protected health information that is being used or shared for this research will be destroyed or no longer used. This is because the information used and *created* during the study may be analyzed for many years, and it is not possible to know when this will be complete.

6. Statement of privacy rights:

- It is your right to refuse to sign this authorization form. If you do not sign this form, you will not be able to participate in the research study. If you do not sign, it will not affect your ongoing treatment or health care coverage.

- You have the right to withdraw your permission for MSK to use or share your protected health information. We will not be able to withdraw all the information that already has been used or shared with others to carry out related activities such as oversight, or that is needed to ensure quality of the study. To withdraw your permission, you must do so in writing by contacting the Study Doctor listed above in the section: "Who can answer my questions about this study?"

- You have the right to request access to your protected health information that is used or shared during this research and that is related to the research or payment for the research, but you may access this information only after the study is completed. You can have access to your medical record at any time. To request this information, please contact the Study Doctor listed above in the section: "Who can answer my questions about this study?" You may also ask the Study Doctor to correct any study related information about you that is wrong.

Notice Concerning HIV-Related Information

Individuals/organizations are prohibited from sharing any HIV-related information without your approval unless permitted to do so under federal or state law. You also have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (888) 392-3644 or the New York City Commission of Human Rights at (212) 306-7500. These agencies are responsible for protecting your rights.

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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. The consent discussion will be documented in the participant"s EMR.

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: _____

(If witness is used for consent discussion, their name must be documented in the EMR.)

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