

## The Ohio State University Consent to Participate in Research

**Study Title:** GENETICS OF HEREDITARY UVEAL (EYE)  
MELANOMA (OSU 06036)

**Principal Investigator:** Frederick H. Davidorf, MD

**Sponsor:** Department of Ophthalmology Internal Funds

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the 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 usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

**1. Why is this study being done?**

This study is being done to study the genetic changes associated with increased risk for development of uveal melanoma and other cancers.

**2. How many people will take part in this study?**

About 400 patients and their family members will be included in the study

**3. What will happen if I take part in this study?**

You will be asked to: 1) read and sign this consent form and HIPAA authorization form; 2) sign a form releasing your medical records and/or tissue samples from previous or upcoming cancer surgeries; 3) agree to allow us to review your medical records regarding

any cancer diagnosis for up to five years; 4) complete a short questionnaire about your medical and family history; and 5) provide a blood, saliva, or mouth wash sample. Most participants will be asked to give a blood sample. If you cannot give a blood sample (because of your diagnosis, or if you have poor veins) you will be asked to give a saliva or a mouth wash sample.

The medical records information that will be gathered in this study includes your demographics, medical history, family history, pathology information on your tumor if you have had cancer, information on any cancer treatment and response, and any related genetic testing results (if available).

**You are being asked to donate: (*person obtaining consent to check all that apply*)**

Blood sample: To collect a blood sample, you would have two tubes of blood drawn (this is about 2 tablespoons worth). This can be done at an OSUMC clinic or laboratory, or at your local doctor's office or outpatient laboratory, and sent to us at our expense. If you are having your blood drawn somewhere other than OSUMC, you may have to pay for the blood draw (about \$10-20).

Cheek cell sample: To collect a cheek cell sample, you would be asked to rinse your mouth with sterile water or a commercially available mouthwash (like Scope). These samples can be collected at home or at OSUMC with a provided kit, and sent back to us at our expense.

Previously-obtained sample: You have already provided a sample for another study which is stored in the Cancer Genetics Sample Bank, and you give permission for use of that sample for this study.

Tissue sample: If you have had cancer or any precancerous growths removed, we may request a piece of the tissue that was removed (this tissue is usually stored by the hospital after surgery). The tissue that we request will be extra tissue that is not needed for your diagnosis or treatment. If you have an upcoming surgery scheduled we may request a fresh piece of tissue from your surgery. This would also be a piece of tissue or cells that was removed but is not needed for your diagnosis or treatment. No extra tissue would be removed for this study. DNA, RNA and or protein will be taken out of this tissue sample and studied.

**4. How long will I be in the study?**

It will take 10-15 minutes to complete all the forms. If you have your blood drawn during a doctor's appointment at OSUMC, this will take about 10 minutes during that appointment. Collecting cheek cell samples will take about 5-10 minutes. This means that

it will take a total of about 20-30 minutes of your time to be in this study. If you plan to make a special trip to your local doctor or outpatient lab to have your blood drawn your travel time will add to the total amount of time it takes to participate in this study. After your paperwork is completed and your samples are collected, you will not be required to do anything else for this study.

**5. Can I stop being in the study?**

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University. If you decide to leave the study, you will need to complete a "Sample Destruction form" and all donated samples that are linkable to you will be destroyed. A record of your entry and withdrawal from the study will be kept. This is done to keep a record of how many people withdrew from the study, and why they withdrew.

**6. What risks, side effects or discomforts can I expect from being in the study?**

The risks of blood draw are: discomfort, pain, bleeding, bruising, infection, lightheadedness, and fainting. Collecting a cheek cell sample may cause some minor, temporary irritation of the mouth. There is no risk for collecting tumor tissue in excess of routine pathological diagnosis. There may also be psychological risks associated with this study. You might find that being involved in cancer genetics research causes you anxiety or upset.

**7. What benefits can I expect from being in the study?**

You will not receive any medical benefit from participating in this study. You will not receive individual results of this study, but instead you will be informed by letter of any overall clinically relevant discoveries made by this study. Such discoveries might help in improvement of the general management of patients with uveal melanoma (including yourself) and their family members.

**8. What other choices do I have if I do not take part in the study?**

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled. Clinical genetic testing may be available for you or your family members, depending on your family history of cancer. If this is an option for you or your family, this will be discussed with you and information on how to have this kind of testing will be given to you. Clinical genetic testing is not part of this study and would be at your or your insurance company's expense.

**9. Will my study-related information be kept confidential?**

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law. Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

If the study involves the use of your protected health information, you may also be asked to sign a separate Health Insurance Portability and Accountability Act (HIPAA) research authorization form.

**10. What are the costs of taking part in this study?**

If you have your blood drawn somewhere other than OSUMC, you may have to pay for the blood draw (about \$10-20). Otherwise there will be no cost to you to participate in this study.

**11. Will I be paid for taking part in this study?**

You will not be paid for taking part in this study. You will not participate in financial gains made by discoveries or commercial ventures developed from the use of your samples.

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

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

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

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

**14. Who can answer my questions about the study?**

For questions, concerns, or complaints about the study you may contact Robert Pilarski, MS, CGC at 1-888-329-1654 or 614-293-7774.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact Robert Pilarski, MS, CGC, at 1-888-329-1654.

**Signing the consent form**

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form.

\_\_\_\_\_  
**Printed name of subject**

\_\_\_\_\_  
**Signature of subject**

\_\_\_\_\_  
**Date and time**

**AM/PM**

_____	_____
<b>Printed name of person authorized to consent for subject (when applicable)</b>	<b>Signature of person authorized to consent for subject (when applicable)</b>
_____	_____
<b>Relationship to the subject</b>	<b>Date and time</b>
	<b>AM/PM</b>

**Investigator/Research Staff**

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

_____	_____
<b>Printed name of person obtaining consent</b>	<b>Signature of person obtaining consent</b>
_____	_____
	<b>Date and time</b>
	<b>AM/PM</b>

**Witness(es)** - *May be left blank if not required by the IRB*

_____	_____
<b>Printed name of witness</b>	<b>Signature of witness</b>
_____	_____
	<b>Date and time</b>
	<b>AM/PM</b>

_____	_____
<b>Printed name of witness</b>	<b>Signature of witness</b>
_____	_____
	<b>Date and time</b>
	<b>AM/PM</b>