ATTACHED: QUESTIONNAIRE, DIRECTIONS & OTHER MEDICAL INFORMATION

- Please read and **COMPLETE** attached questionnaire in full prior to arriving.
  - Please note that the questionnaire is over 20 pages long and will take some time to complete.
- Please bring the questionnaire with you on the day of your appointment.
- Please complete in full the name, address & telephone number of your referring physician (physician requesting you be seen at the Pigmented Lesion Group)

HEALTH INSURANCE REFERRALS

- Please obtain any necessary health insurance referrals from your Primary Care Physician at least 7 days prior to your appointment.
- Our provider number to give to your PCP for your referral is **NPI: 122 542 6349**
- **If you are scheduled to see our surgeon and require referrals, please obtain a referral for this appointment as well.**

  Dr. Giorgos Karakousis: 187 198 1985

- Your appointment may need to be rescheduled if a referral **is not** obtained.

❖ **Please expect to be here approximately 3 hours for this visit if you are only scheduled to see one physician. If you are scheduled to see the surgeon this day as well, please expect to be here approximately 5-6 hours to complete both appointments, as well as any pre-operative testing.**

APPOINTMENT ADDRESS
Perelman Center for Advanced Medicine
Department of Dermatology
1st Floor, South Pavilion
3400 Civic Center Blvd.
Philadelphia, PA 19104
***Please see enclosed driving directions.**

Please plan to be here ***at least 30 minutes*** prior to your appointment to allow time for the check in process and to allow time for potential issues with parking (there are times when both the garage and valet are closed, and you must park several blocks away).

Please have your insurance card, photo ID, copayment and **questionnaire ready** when you check in.

Our office can be reached at 215-360-0909 Monday-Friday 8:00am-4:00pm

NO SHOW POLICY

If you fail to show up or cancel your appointment less than 24 hours before your scheduled time, you may be subject to a **new patient, no show/cancel fee of $70.00.**
Please be aware any slide review will have already happened and been submitted to your insurance company.

UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM

Pigmented Lesion Group – Medical History & Registration – New Patient

Name:_____ Date of Birth:_____ MRN#_____ PLG#_____

Please try to answer all the following questions about your medical history and demographics (information on young children should be completed by parents). Please make sure you fill out all of the 5 pages. Use the reverse side of a page if you need more room. Our nursing staff can assist you when you are called to an exam room if you are unable to answer any questions.

Have you ever been told by a doctor that you had any of the following:			Where was it on your body?	Date(s) of surgery?	Name of doctor(s) who treated you?	Hospital, City, and State where treated?
Melanoma skin cancer	☐ No	☐ Yes				
Removal of a mole	☐ No	☐ Yes				
Basal cell skin cancer	☐ No	☐ Yes				
Squamous cell skin cancer	☐ No	☐ Yes				
Other non-melanoma skin cancer	☐ No	☐ Yes				
Cancer (other than skin cancers)	☐ No	☐ Yes				

List year and type of all other past/present major illnesses:

List year and reason for all other past major surgeries:

List all prescription and over-the-counter medications: (include birth control pills, vitamins, aspirin, Advil, Motrin and natural herbs).

LIST OUT ON ATTACHED

Are you allergic to any medications? ☐ No ☐ Yes
If yes, please list medications and type of reaction:

Do you check your skin regularly for changes? ☐ No ☐ Yes

Have any of your moles changed or have new moles or bumps appeared on your skin? ☐ No ☐ Yes
If yes, please describe:

Have you been experiencing any of the following?

Unexplained weight loss	☐ No	☐ Yes	Bowel or bladder problems	☐ No	☐ Yes
Debilitating fatigue	☐ No	☐ Yes	Chest pain, cough	☐ No	☐ Yes
Swelling or tenderness in neck, armpits, groin	☐ No	☐ Yes	Stomach pain, nausea, vomiting	☐ No	☐ Yes
Severe or persistent headaches	☐ No	☐ Yes	Joint or bone pain	☐ No	☐ Yes
Dizziness, numbness, unusual sensations	☐ No	☐ Yes	Other problems with pain	☐ No	☐ Yes_____
Difficulty swallowing	☐ No	☐ Yes	Depression or anxiety	☐ No	☐ Yes
Special dietary problems	☐ No	☐ Yes	Limitations in physical activity	☐ No	☐ Yes_____
			Inability to perform activities of daily living without help (ex. bathing, dressing, walking)	☐ No	☐ Yes_____

Are there any special problems that you would like to discuss with the doctor today? ☐ No ☐ Yes
If yes, please describe:

What language do you use primarily? ☐ English ☐ Other:_____

Do you learn best by:
☐ Reading ☐ Listening ☐ Seeing a demonstration ☐ Other _____

Information reviewed and discussed with patient by:

Pigmented Lesion Group – Medical History & Registration – New Patient

Name:_____ Date of Birth:_____ MRN#_____ PLG#_____

A history of melanoma in a blood relative is an important part of your medical history. A confirmed history can indicate a need for preventive screening exams and counseling about lifestyle factors such as sun exposure for both you and your immediate family. Because of the importance of family history, we try to determine your relationship to other Pigmented Lesion Group patients as well as to any other relatives you may have with melanoma. Please be aware that information about your family history could be shared with other family members who may become patients here also.

Has anyone else in your family been a patient of the Pigmented Lesion Group? ☐ No ☐ Yes, please list below:

Full name of relative	Birth date (or age)	Relationship to you	Any address information that you can provide

Have any other blood relatives (not listed above), had melanoma skin cancer? ☐ No ☐ Yes, please list below:

Full name of relative	Birth date (or age)	Relationship to you	Date of first melanoma?	Is the relative alive?	Date and cause of death, if deceased.

How many people in your immediate family* have had cancer (other than skin cancer)? (put zero if none): _____
*(*Immediate family includes parents, full brothers and sisters, half brothers and sisters, and biological children. Do not include family members who are not related to you by blood, such as a spouse, stepchild, or adopted child.)*

How many full brothers and sisters do you have, either living or deceased? (put zero if none): _____

How many half brothers and sisters do you have, either living or deceased? (put zero if none): _____

How many biological children do you have, either living or deceased? (put zero if none): _____

Women's hormone levels may influence how moles and melanoma behave. Your doctor always should know if you might be pregnant, and we would also like some additional pregnancy information. This is so we can learn more about the biological effects of gender and reproductive hormones.

For females only – pregnancy history.

Have you ever been pregnant?
- ☐ No
- ☐ Yes

Are you currently pregnant?
- ☐ No
- ☐ Yes

Are you still having menstrual periods?
- ☐ Yes (but currently/recently pregnant)
- ☐ No, stopped/stopping due to natural menopause
- ☐ No, stopped due to causes other than natural menopause
- ☐ No, have never had menstrual periods

How many times have you been pregnant? _____
(Count all pregnancies which resulted in a live birth or went full term)

What month and year did your last pregnancy end? _____
(Use today's date if pregnant now)

Pigmented Lesion Group – Medical History & Registration – New Patient

Name:_____ Date of Birth:_____ MRN#_____ PLG#_____

Your eye color, hair color, skin color, and skin's tendency to burn are also important parts of your medical history that can indicate a need for preventive screening exams and counseling about lifestyle factors such as sun exposure. Please choose the one answer for each of the following questions which best describes you.

Which of the following best describes your natural eye color?

- ☐ Blue
- ☐ Green
- ☐ Grey
- ☐ Hazel
- ☐ Light brown
- ☐ Dark brown
- ☐ Black

Which of the following best describes your natural hair color when you were a teenager? (put current hair color for children)

- ☐ Blond
- ☐ Red
- ☐ Light brown
- ☐ Brown
- ☐ Black

Which of the following best describes you?

- ☐ White
- ☐ Black
- ☐ Asian/Pacific Islander
- ☐ American Indian/Alaskan native
- ☐ Other, please state:_____

As a teenager, how would your skin burn if you had no tan and were exposed to strong sunlight* for one-half hour without protective sunscreen?
*(*Strong sunlight is noonday sunlight on the brightest, clearest day in summer.)*

- ☐ Would get painful sunburn with blisters
- ☐ Would get painful sunburn, but not any blisters
- ☐ Would get a non-painful sunburn
- ☐ Would not get any sunburn
- ☐ Not a teenager yet

As a teenager, how would your skin appear after repeated and prolonged exposure to sunlight?

- ☐ Not tan at all
- ☐ Lightly tanned
- ☐ Moderately tanned
- ☐ Very brown and deeply tanned
- ☐ Not a teenager yet

What is your current occupation? _____

Please read and complete the signature and date lines on the following research and teaching consent.

Hospital of the University of Pennsylvania
Pigmented Lesion Group
Research and Teaching Consent Form

As a patient of the University of Pennsylvania Pigmented Lesion Group, I understand that clinical information is gathered into my medical record as part of my care and that during the course of my care biopsies or excisions of skin lesions may be clinically indicated.

I consent to the use of my medical records and residual surgical material (i.e., the part of a pathology specimen that is not used for diagnosis) by the Pigmented Lesion Group for medical education and research. I understand that any information about me that is used for education and/or research purposes will be treated confidentially and I will not be personally identified in the reporting of the results. I also understand that use of these materials for research or teaching will not impact directly on my clinical care.

I understand that my consent is entirely voluntary and that I may refuse the use of my clinical information/materials for medical education/research purposes without affecting the health care I receive at the Hospital of the University of Pennsylvania.

I understand that I may ask any questions I have about the educational and research activities of the Pigmented Lesion Group at this time. If I have any further questions, I may contact Nancy Jones, R.N. or Michael Ming, M.D. at 215-662-6926.

Please sign here ➡ _____ _____
Patient's signature Date
(Parent or guardian's signature if under age 18)

Name:_____ Date of Birth:_____ MRN#_____ PLG#_____

Please complete the signature and birth date lines on the following release which will be used to request copies for your Pigmented Lesion Group chart of any medical records you may have relating to melanoma, pigmented lesions, or related cancers.

Please sign the below form even if you think all of your medical records are already here. The rest of the form can be left blank (we will fill in the rest if necessary).

Medical Records Release

I, _____ hereby request that copies of the following medical records:
Print name

Operative Records Discharge Summaries

Pathology Reports Microscopic Slides Paraffin Blocks

Radiology Reports Laboratory Reports

relating to:

Approximate treatment/admission date(s): _____

Procedure(s): _____

Under the care of Dr(s): _____

Hospital or Laboratory Name: _____

be sent to:

Hospital of the University of Pennsylvania
Department of Dermatology
The Pigmented Lesion Group
Maloney – 2
3400 Spruce Street
Philadelphia, PA 19104

Please sign here ➡ _____ _____
Patient's signature Date of Birth
(Parent or guardian's signature if under age 18)

_____ _____
Witness Request Date

Pigmented Lesion Group – Medical History & Registration – New Patient

Name:_____ Date of Birth:_____ MRN#_____ PLG#_____

Please complete the following information.

Name:		Birth Date:	
Address:		Gender:	
City:		Home Phone Number:	
State, ZIP code:		Work Phone Number:	
Email address:		Cell Phone Number:	
Social Security #:		Call during day at home or work number?	

Please provide contact information for your next of kin and an *alternate* emergency contact.

Next of kin:		Emergency contact: (Relative or friend NOT residing at same address)	
Relationship to you:		Relationship to you:	
Address:		Address:	
City, State, ZIP code:		City, State, ZIP code:	
Phone Number:		Phone Number:	

Please provide the names, addresses and phone numbers of the doctors who should receive copies of your exam notes. Your primary care physician or family doctor should always be on the list. Check the type of care you receive from each doctor on the list.

Referring doctor:

Name: _____
Address: _____
Address: _____
Phone Number: _____
Fax Number: _____

Type of Care:

- ☐ Primary Care (family doctor)
- ☐ Dermatologist
- ☐ Surgeon
- ☐ Oncologist
- ☐ Other:_____

Copies should also be sent to:

Name: _____
Address: _____
Address: _____
Phone Number: _____
Fax Number: _____

- ☐ Primary Care (family doctor)
- ☐ Dermatologist
- ☐ Surgeon
- ☐ Oncologist
- ☐ Other:_____

Name: _____
Address: _____
Address: _____
Phone Number: _____
Fax Number: _____

- ☐ Primary Care (family doctor)
- ☐ Dermatologist
- ☐ Surgeon
- ☐ Oncologist
- ☐ Other:_____

Name: _____
Address: _____
Address: _____
Phone Number: _____
Fax Number: _____

- ☐ Primary Care (family doctor)
- ☐ Dermatologist
- ☐ Surgeon
- ☐ Oncologist
- ☐ Other:_____

Medical Information

Please complete in full and bring with you to your appointment

PLEASE LIST ALL MEDICATIONS BELOW:

Name of Medication	Dose of Medication	How often taken
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		
11.		
12.		

Please note: HAND WRITTEN OR A TYPED COPY LISTING YOUR CURRENT MEDICATIONS IS OKAY TO ATTACH TO THIS SHEET.

Social History

(Please circle)

Alcohol consumption (please circle) **NO YES** How many drinks per week: ____ Type:_____

QUIT When :_____

Tobacco use	**CURRENTLY A SMOKER**	**Type: (please circle)**	Cigarettes	Cigar	Pipe
	How much do you currently smoke:			**Year started:**	
	QUIT: Year:	How long did you smoke?	How much did you smoke?		
	NEVER SMOKED				
Smokeless Tobacco Use	**NO**	**YES**	**TYPE: (please circle)**	Snuff	Chewing Tobacco Other:_____
Drug use	**NO**	**YES**	Type:		

PRINT YOUR NAME AND DATE OF BIRTH BELOW:

_____

HEALTH SCREENING ASSESSMENT

To be completed by patient
DEPARTMENT OF DERMATOLOGY

Patient Name: Please print	Date of Birth:	Today's date:

1.	How do you learn best by: (circle all that apply)		
	Reading	Listening	Pictures
	Demonstration	Video	Other:

2.	Have you had an <u>unintentional</u> weight loss of more than 10 pounds over the past 3 months?	NO	YES	If YES, please comment:
3.	Do you have difficulty grooming, bathing, or dressing?	NO	YES	If YES, please comment:
4.	Have you fallen more than once in the past year, or hurt yourself in a fall?	NO	YES	If YES, please comment:
5.	Do you feel you are at RISK of falling?	NO	YES	If YES, please comment:
6.	Are you experiencing any abuse or violence at home or in any personal relationship?	NO	YES	If YES, please comment:
7.	Do you have an advance directive, living will, healthcare agent or healthcare power of attorney?	NO	YES	If YES, please comment:
8.	During the past month have you felt down, depressed, or hopeless?	NO	YES	If YES, please comment:
9.	Should we be aware of any cultural or religious beliefs that may affect your healthcare?	NO	YES	If YES, please comment:
10.	Are you experiencing any pain? If Yes please rate your pain on a scale of 0-10. 0-No Pain & 10-Worst Pain You Ever Felt	NO	YES	Please rate your pain: 0 1 2 3 4 5 6 7 8 9 10

UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM

The Pigmented Lesion/Melanoma Group

Patient Name_____ Date of birth___/___/____

Permission to call telephone contact sheet

Privacy regulations are a good thing, but they can sometimes make it challenging for your doctors to communicate with you. In the form below, we request your permission to leave you a message that your doctor needs to talk to you or other information that your doctor wants to communicate with you.

- When calling your home, cell, or work phone number, is it okay to leave a detailed message (which may include information about your medical condition) with whoever answers the phone or on the answering machine?

Home phone number: (_____)_____-_____

☐ OK to leave message, on answering machine or with anyone who answers
☐ OK to leave message, on answering machine or only with the following people:
_____
☐ OK to leave message, only with the following people:
_____

Cell phone number: (_____)_____-_____

☐ OK to leave message, on voicemail or with anyone who answers
☐ OK to leave message, on voicemail or only with the following people:
_____

Work phone number: (_____)_____-_____
What times are you normally at work?_____

☐ OK to leave message, on voicemail or with anyone who answers
☐ OK to leave message, on voicemail or only with the following people:
_____
☐ It is OK to call me at this number and leave a message on my work voicemail (if I have one), but please do not reveal any information about me to anyone at work

Please make sure that you have given us permission to leave you a message on answering machine or voicemail by at least one of the methods above. If you do not give us permission, we can not leave a message, no matter how urgent it is. Please make it as easy as possible for us to get in touch with you.

Please also make sure that we have
-**at least** one phone number where you can be reached during the **day on a weekday**
-**at least** one phone number where you can be reached in the **evening**

Please circle the
Best numbers during the day: HOME CELL WORK Other:_____
and
Best numbers during the evening: HOME CELL WORK Other:_____

RESEARCH INFORMED CONSENT AND HIPAA AUTHORIZATION FORM

Melanoma Program-Studies of Melanoma and Other Skin Cancers

(Melanoma Program-SMOSC)

Penn Medicine
The Wistar Institute

(UPCC 08607 & IRB 703001)

Principal Investigator: **Giorgos C. Karakousis, MD**

Department of Surgery
Hospital of the University of Pennsylvania
3400 Spruce Street, 4 Silverstein
Philadelphia, PA 19104

Co-Investigators:

Lynn Schuchter, MD
Ravi Amaravadi, MD
Xiaowei (George) Xu, MD, PhD
David Elder, MB, ChB
Naomi S. Balzer-Haas, MD
Meenhard Herlyn, DVM, DSc
Tara Mitchell, MD
John Miura, MD
Robert Brody, MD
Brian Capell, MD, PhD
Katherine Nathanson, MD
Christopher Miller, MD
Michael Ming, MD
Rosalie Elenitsas, MD
Jessie Villanueva, PhD
Joseph Sobanko, MD
Phyllis Gimotty, PhD
Emily Chu, MD, PhD
Gerald P. Linette, MD, PhD
John Nicholas Lukens, MD

Emergency Contact: Giorgos C. Karakousis, MD
(215) 662-2083

Study Contact: Ahron J. Flowers, MS
(215) 360-0911
aflow@pennmedicine.upenn.edu

24 Hour Emergency Contact: (215) 662-4000 Ask for Oncologist on Call

Introduction:

You are being invited to take part in this research study. You are being asked to volunteer since you and/or your Physician has concerns regarding your skin health. Your participation is voluntary which means you can choose whether or not you want to take part. If you choose not to take part, there will be no loss of benefits to which you are otherwise entitled. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. Now that a member of the research team has talked to you about this study, you are being given this consent form to read which explains your participation. You may also decide to discuss this study with your family, friends, or family doctor. You may find some of the medical language difficult to understand. Please ask the study doctor and/or the research team about this form. If you decide to take part, you will be asked to sign this form.

Why am I being asked to volunteer?

You are being asked to take part in this research study, because you are 16 years or older, and you may meet at least one of the following categories:

1. You have been diagnosed with melanoma or other skin cancer, or you are at risk of developing melanoma or other skin cancer; and you will be undergoing a biopsy (or surgery) at Penn Medicine or at another institution as part of your clinical care
2. You have been diagnosed with melanoma or other skin cancer, and you have already undergone a biopsy (or surgery) for anther research projects or for clinical care at Penn Medicine or at another institution. You have voluntarily agreed to have a biopsy and/or donate blood for research purposes for this study.

What is the purpose of this research?

The purpose of this research is to save samples for ongoing and future cancer-related research for finding better ways to detect and treat skin cancers. Research using blood and tissues is an important way to try to understand human diseases. Doctors and other medical scientists want (1) to find better ways to detect cancer early, (2) to determine how cancer spreads and resists current types of treatment, (3) to treat and, if possible,

cure patients who have cancer, and (4) to determine how cancer risk may be inherited in some families. To do these things, they need more information about the causes and behavior of cancer. Doctors and other medical scientists therefore want to study samples of cancer cells (tumor tissue), normal cells from around the tumor, and blood from patients with cancer, and, in some instances, from their relatives. Five possible forms of specimens may be collected depending on the samples that have previously been obtained or will be obtained for you: blood, fresh tumor tissue, fresh non-tumor tissue, lymph nodes, leftover body fluid (that obtained by diagnostic or therapeutic pleurocentesis procedure in which a needle or catheter is inserted into chest cavity to remove body fluid, or paracentesis procedure in which a needle or catheter is inserted into abdomen to remove body fluid), and virtual biospecimens (currently being housed elsewhere at Penn Medicine or at other institutions).

How long will I be in the study? How many other people will be in the study?

There is no duration and no limited number of people for this study. You will be in this study as you are followed for your clinical care at Penn Medicine. We expect to enroll as many people as possible in this study.

What are you being asked to do?

Providing Samples of Tissue Obtained for Clinical Care:

1. **If you will be undergoing a biopsy (or surgery) for melanoma or other skin cancer**, you will have your cancer, lymph node, and/or other abnormal tissue removed. Your doctor will collect some tissues as part of your treatment, do some tests and/or for research purposes. The investigators for this study would like to keep some of the tissue (if applicable), for ongoing or future research. There will be no additional tissue removed beyond what is routinely removed in biopsy or surgical procedures. We will only use the tissue that would have been normally discarded. If you agree to take part in this study, a small sample of the tissue that has been removed (usually about 1 cubic centimeter, the size of a small sugar cube or less) will be collected and kept in a tissue bank. The tissue placed in the tissue bank will not be needed for diagnosis or management of your abnormal tissue or tumor. In addition, if a sample of your normal tissue is removed we would like to obtain a similar sized small portion of normal tissue to compare it to the tumor tissue. The normal tissue may include skin, lymph node, and/or other tissue removed in biopsy

or surgical procedures. In some cases, there may be no leftover tissue from your biopsy procedure, however, we will use the slides or archived tissue blocks after all the clinical care assessment has been completed.

If you will undergo pleurocentesis or paracentesis procedure for your clinical care such us diagnostic or therapeutic purposes, we may collect leftover body fluid that normally will be discarded.

2. **If you have undergone a biopsy (or surgery) for melanoma or other skin cancer at Penn Medicineor at another institution**, after such tests are completed, there may be leftover tissue that is stored or "archived" in the form of small wax blocks (paraffin blocks) in the Department of Pathology or elsewhere. In addition to "archival" tissue blocks, tumor tissue from previous surgeries may have been collected, frozen and stored. We would like to ask your permission to contact the institution and department (Penn Medicine or non-Penn Medicine entity) that currently has your body tissue(s) for possible research use. For the "archived" tissue block, if you agree, we would ask for use of archived tissue by following the asked department/institution (Penn Medicine or non-Penn Medicine entity)'s own standard procedure for patient protection and releasing the archived tissue for research.

Research Biopsy:

If you agreed, Punch Biopsy (a small round piece of skin, usually the size of a pencil eraser, is obtained using a sharp, hollow instrument); or Fine Needle Aspiration (FNA) (a small, fine-gauge needle is inserted into the area and the needle is rocked gently to obtain as much tissue as possible), or Core Needle Biopsy (CNB) (much like a FNA, a slightly larger, hollow needle is used to withdraw small cylinders (or cores) of tissue from the abnormal area) will be performed for research purposes only, to donate a sample of tissue, such as a clinically accessible tumor; different layers of skin tissue that may include the epidermis (the thin outer layer of the skin), the dermis (the middle layer of the skin. that is made up of blood vessels, lymph vessels, hair follicles, sweat glands), and/or the subcutaneous layer (the deepest layer of skin) etc.

Blood Samples:

Additionally, you will be asked to donate a blood sample of up to 40 mL (about 1.35 fluid ounces, about 2.7 tablespoons) or less in most cases. For some immune studies, 65 mL (about 2.2 fluid ounces 4.3 tablespoons) or less of blood may be collected. This blood

will be collected by an ordinary blood drawing procedure. Over the course of your clinical care, you may also be asked to contribute additional blood at later visits, 40 mL or less in most cases, and 65 mL in some immune studies, total up to 65 ml (about 2.2 fluid ounces, 4.3 tablespoons) or less at each time.

If specimens to be collected at a location other than Penn Medicine, a copy of this signed consent form and a request of tissue release and instruction may be sent to the designated location, and we will depend on their local standard operation procedures for the specimen release and transfer.

Review of your health status:

We hope to follow you over time to find out what happens to your health. We will gather information about you that will help us better understand your overall health status and other information about you. By signing this consent form, you have agreed and given us your permission on follows:

1) To use your medical information at UPHS for research studies, your medical information including your Electronic Medical Record (EMR) will be reviewed by researchers for an unlimited time, and unless you give us notice that you are not be willing to stay in this study.

2) If you are not seeing doctors here at Penn Medicine, we may contact you, your physicians or other health care providers via your permission (you would be asked to sign a separate medical release consent form), or other contacts you have provided so that you can update your health information. This may include a brief survey/questionnaire sent to you or your doctor, or a phone call. If contacted by mail, a prepaid envelope will be provided to return the survey/questionnaire.

3) To provide researchers with information about you to determine if you would be eligible for future specific research studies. This current consent is NOT a consent to participate in those other research studies. We would like to ask your permission to contact you for future specific research studies.

Research on family members:

In some cases the researchers may want to obtain information about family members or may want to request a blood sample from family members. In these cases, we will ask

you to provide our research contact information to them, and when they contact us, we will discuss and separately consent for the research with them directly.

What will researchers do with the samples (blood, body fluid and tissue) obtained for this research?

The fresh tissue samples obtained for this research study may be tested immediately or may be frozen and examined later. The samples will then be given to researchers, either at Penn Medicine or the Wistar Institute, and other collaborating institutions and profit companies, for research studies. Samples will be tested but not limited for cancer markers or immune assays, etc. Including sequencing of some or all of your genes (deoxyribonucleic acid, or DNA). Markers refer to the genes (DNA), gene products, ribonucleic acid (RNA), and proteins that are expressed in tumors and in normal tissues or blood. The study of such markers is essential for developing cancer detection tests, cancer treatment strategies, and new cancer therapies.

Human DNA is organized in pieces called genes that provide the instructions needed to make our bodies work. Some rare diseases are caused by a single change in DNA (one gene). Diseases like melanoma or other skin cancers may be caused by several genes that work together. One of the purposes of this research study is to improve our understanding of the genetic basis of melanoma or other skin cancers, as well as associated diseases and treatment related conditions. DNA holds the instructions to make RNA, the substance that makes proteins (the building blocks of our bodies). Sometimes changes in how RNA is expressed can lead to the development of diseases such as or other skin cancers. Another purpose of this research study is to improve our understanding of how gene expression in blood and tissue (if applicable) is related to melanoma or other skin cancers, as well as associated diseases and related conditions. RNA holds the instructions for making protein. Human beings are made out of proteins. A separate purpose of this study is to improve our understanding of protein variations in the blood and tissue (if applicable) as they are related to melanoma or other skin cancers, as well as associated diseases and treatment related conditions. Thus, the ultimate purpose of this research is to study variations in DNA, RNA and Proteins, with the goal of better diagnosing, treating and curing melanoma or other skin cancers, as well as associated diseases and treatment related conditions.

The frozen samples of your tissue and/or blood cells or their extracts will be kept in a tissue bank. Your tissue/or blood sample may be kept until you indicate that you would like it to be discarded or until no cells or their extracts remain in the sample. Blood that is drawn will be used to test immune reaction against melanoma or other skin cancers, to establish cell cultures, or to isolate certain cells from the blood. Some cells obtained from your body may be used to establish a cell line or for creating xenograft tumor model in mouse that may be shared in the future with other researchers. A cell line is one that grows indefinitely in the laboratory. Cell lines may be useful because of the characteristics of the cells and/or the products they may produce. A mouse xenograft is created by transferring tumor cells and letting them grow in mouse, one of the important usages of the mouse model is to help testing anticancer drugs. If you prefer not to allow storage of your tissue and/or blood cells, research tests on them, or cell lines establishing and xenograft tumor mouse model creating from them, if you are not willing for using your collected tissue for these purposes, you are not be able to participate in this study.

Things to think about:

The choice to let us keep obtains tissue blood and/or fluids for research are up to you. **No matter what you decide to do, it will not affect your care.** You may still take part in any other ongoing research studies at Penn Medicine or elsewhere. It is likely that the research being done with your tissue will not help you personally. However, it may help others who have cancer and other diseases in the future. Reports about research done with your tissue or blood will not be given to you or your doctor. The research will not have an effect on your care.

If you decide now that your tissue blood and/or fluids can be kept for research, you can change your mind at any time. Should you decide to withdraw your participation in this study, contact the Principal Investigator Giorgos Karakousis, MD, listed on the first page of this consent form, and let him know that you do not want your tissue or blood to be used for research anymore. As per your request the tissue or blood will no longer be used for research. However, specimens that already have been analyzed, as well as any results or information already obtained prior to withdrawing from the study cannot be removed or discarded.

Your blood, tissue and/or fluids will be used only for research collaborations that could involve the following entities: government, profit or non-profit organizations, and will not be sold. Although the research done with your tissue may help to develop new products in the future, you will not be paid for allowing your tissue to be used. Similarly, your tissue/blood will be collected and stored at no cost to you.

There is a small possibility that new diagnostic tests may become available after you have consented to the use of your archived tissue, though this situation is rare. In the future, people who do research on your samples may need to know more about your health. When the hospital or clinic gives these researchers reports about your health, they will not be given your name, address, phone number or other personal health information. However, designated Penn Medicine research study staff will have access to identifying information such as your name, address and phone number in order to update your health information for the study, and if you consent, to contact you at a later time.

Your blood, tissue and/or fluids may be used for genetic research (about diseases that are passed on in families). Your blood may also be used to determine if markers within your blood are associated with melanoma or other skin cancer risks, outcomes and treatment. Your blood and tissue (if applicable) will also be used in research exploring diseases associated with melanoma or other skin cancers, as well as treatment related conditions.

Any tissue or blood obtained for the purposes of this study becomes the property of the Penn Medicine or the Wistar Institute. Penn Medicine may retain, preserve or dispose of these specimens, and may use these specimens in research, which could result in grant applications or commercial applications. You will not receive money for donating blood or tissue, nor will you receive money for any future commercial ventures. Your tissue or blood will only be used for research.

Risks:

Risks of using stored tissue:

For your "archived" tissue blocks, we will follow the asked department/institution's own standard procedure for patient protection and releasing the archived tissue for research

at Penn Medicine or non-Penn Medicine entities, when we request the release. This attempt is our effort in making sure the removal of said blocks/tissues will have no effect on your future clinical care. However, there is potential risk that the entire stored sample may be used up and therefore may not be available for future clinical assessments as part of your routine care.

Punch biopsy and Core needle biopsy:

The possible risks of punch biopsy and core needle biopsy may include pain, discomfort, soreness, redness, swelling, bleeding, bruising, drainage from the biopsy site, abnormal wound healing, scar, fever, infection, and allergic reaction to the medication used to numb the skin over the biopsy site.

Fine needle aspirate:

The possible risks of fine needle aspirate may include pain, discomfort, soreness bleeding, bruising, swelling, and infection at the needle insertion site.

Blood Draws:

In most cases we will add research blood tubes to your clinical labs, in some cases if a research specific blood draw is needed, trained personnel will obtain the blood samples. You will be checked closely to see if complications due to blood drawing occur. Complications that may arise as a result of blood collection are typically minimal and may include bruising, swelling, fainting, bleeding, formation of small blood clot and/or infection at the needle insertion site.

Breach of Confidentiality:

Another great risk is the release of information from your medical records. The investigators will protect your records so that your name, address, phone number and social security number will be kept private. The chance that this information will be given to someone else is very small. You will not be able to regain ownership of your sample(s) once they have been donated.

Some of the future studies may or may not be testing the genes that you inherited from your parents (also known as genetic testing).

Costs and Financial Risks:

If you agree to participate in this study, your tissue and blood samples will be stored at no cost to you. Any research tests involving your tissue and blood samples will be performed at no cost to you.

Benefits:

You should not expect your condition to improve as a result of participating in this research. However, new information about cancer, derived from this research, could help doctors identify new methods for early detection, new treatments, and possibly, cures. This study may provide information leading to the discovery of genes involved in causing cancer. You will not receive any personal information from this study.

Alternatives:

You have the alternative of not participating in this study. Your participation is completely voluntary and will not affect your medical treatment now or in the future.

Compensation:

There will be no financial compensation for participation in this study.

Confidentiality & Privacy Rights:

Your privacy is very important to us and we will make every effort to protect it. All information collected in this study will be kept strictly confidential, with the exception of what is required by law. Your tissue and blood samples used in this research study will be stored with a confidential code, and your name will not be included with any data shared with outside Penn except as noted previously. The key connecting your name to your code number will be held in a separate, secure location. No information about family relationships that may be discovered as a result of this research will be communicated to family members.

Organizations that may look at or copy your records for quality assurance and data analysis include groups such as: The National Cancer Institute (NCI), Federal Drug Administration (FDA), and Penn Medicine, including the University of Pennsylvania's Institutional Review Board (IRB), which is a group of people who review the research to

protect your rights. If publications or presentations result from this research; you will not be identified by name or in any other way.

What is an Electronic Medical Record?

An Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record.

If you are receiving care or have received care within the Penn Medicine (outpatient or inpatient) and are participating in a Penn Medicine research study, results of research-related procedures (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by Penn Medicine.

Once placed in your EMR, these results are accessible to appropriate Penn Medicine workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by Penn Medicine to be appropriate to have access to your EMR (e.g. health insurance company, disability provider, etc.).

What information about you may be collected, used or shared with others?

The following personal health information will be collected, used for research and may be disclosed or released to other researchers:

- Personal and Demographic information (e.g. name, address, telephone number and/or other contact information, date of birth, gender)
- Medical history including personal history of cancer, surgical history including previous biopsies, pathology reports, and/or slides if applicable, radiographic, study results, laboratory test results of interest, and other materials
- Family history (diagnoses)
- Medications (including doses), and other treatment history
- Characteristics of your tumor(s) or blood
- Tissues, blood samples or body fluid as described in previous sections for isolation of material (such as cells and cellular constituents)

Why is your information being used?

Your information is used by the research team to contact you during the study. Your information and results of tests and procedures are used to:

- do the research
- oversee the research
- to be sure the research was done correctly

Who may use and share information about you?

Access to your personal health information for this research study will be restricted to the following individuals:

- The principal investigator and the investigator's study team (other Penn Medicine staff associated with the study)
- Penn researchers with approval from the Melanoma Steering Committee (MSC) and approval from the Institutional Review Board (IRB) whenever required.

Authorized members of the workforce of Penn Medicine and support offices including Institutional Review Board (IRB), Office of Clinical Research (OCR), Office of Regulatory Affairs (ORA), Abramson Cancer Center Clinical Trials Scientific Review and Monitoring Committee (CTSRMC), Data Safety and Monitoring Committee (DSMC), etc., who may need to access your information in the performance of their duties (for example, for research oversight and monitoring), Members of the Abramson Cancer Center Tumor Tissue and Biospecimen Bank (TTAB), and Database & Applications Group (DAG)The Wistar Institute.

Who, outside of the Penn Medicine, might receive your information?

As part of the study, research data about you may be shared with other collaborating institutions and for profit companies, or National Institutes of Health (NIH), and other central repositories developed special data (information) banks that analyze data and collect the results of whole genome studies. These central banks will store your genetic information and give it to other researchers to do more studies. We do not think that there will be further risks to your privacy and confidentiality by sharing your samples and whole genome information with these banks. However, we cannot predict how genetic

information will be used in the future. The samples and data provided to other collaborating institutions and non-profit/or profit companies will only be identified by a code number, your name or other directly identifiable information will not be given out. Every effort will be made to keep all information about you confidential.

The Principal Investigator and the study team may disclose your personal health information, including the results of the research study tests and procedures to the NIH and NCI (Bethesda, MD), the Federal Drug Administration (FDA) (Bethesda, MD) or other governmental agencies as required by law. On rare occasions, disclosure to a third party or parties may be required by law. Because of the need to release information to these parties, absolute confidentiality cannot be guaranteed. Once your personal health information is disclosed to others outside the Penn Medicine, it may no longer be covered by federal privacy protection regulations. Any additions to the above list will be subject to University of Pennsylvania procedures developed to protect your privacy.

How long may Penn Medicine use or disclose your personal health information?

Your authorization for use of your personal health information for this specific study does not expire. Your information may be held in a research database. However, the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization
- The University of Pennsylvania's Institutional Review Board grants permission
- As permitted by law.

Can you change your mind about giving permission for use of your information?

Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the Principal Investigator (Dr. Giorgos Karakousis on the first page of this consent form). There are several options for withdrawal:

- You may request that your unused specimens be destroyed but data already associated with it remain in the database. If the specimens have not been used at

the time of the request, the specimens will be destroyed. However, specimens that already have been analyzed, as well as any results or information already obtained prior to withdrawing from the study cannot be removed or discarded.

- You may choose to have investigators retain the identified samples as part of your routine clinical care but not for additional research.
- You may request that your specimen be retained as a de-identified specimen with only aggregate data associated with it.

If you withdraw your permission, you will not be able to stay in this study.

What if you decide not to give permission to use and give out your health information?

Then you will not be in this research study but your treatment will not be affected by your decision.

Subject Rights:

If you would like further information regarding your rights as a research subject, you may contact the Director of Regulatory Affairs at the University of Pennsylvania by calling (215) 898-2614.

If you have any questions pertaining to your participation in this research study, you may contact Dr. Giorgos Karakousis at (215) 662-2083 (office) or Ahron Flowers at (215) 360-0911 (office).

You will be given a copy of this research subject Informed Consent and HIPAA Authorization Form describing your confidentiality and privacy rights for this study.

Consent of Subject:

By signing this document you are permitting the Penn Medicine to use and disclose personal health information collected about you for research purposes as described above. Upon signing below, you agree that you have read and understand this consent form, the study has been explained to you, your questions have been answered, you have time to make your decision, you have been given the names of study staff that you can contact if you need assistance or if you have any additional questions or concerns,

and you are willing to take part in this research study, and you are willing to be contacted for future research studies. You will receive a copy of the signed consent form. If you are a child less than 18 years old, you have talked this over with your parents/guardians before you decide to participate. Your parents need to give their permission for you to take part in this study. You understand that even if both of your parents say "yes", you can still decide not to be in this study. Signing your name below means that you agree to be in this study. You and your parents/guardians will be given a copy of this form after you sign it.

_____ _____

Name of Participant (please print) Signature of Participant

Date: _____

_____ _____

Name of Person Obtaining Consent Signature of Person Obtaining Consent

Date: _____

For use by parents/guardians for parental/guardian signature:

For children less than 18 years old, the authorization is given by the parent or guardian listed below. (The child needs to sign above):

_____ _____

Name of Parent/Guardian (please print) Signature of Parent/Guardian

Date: _____

_____ _____

Name of Second Parent/Guardian (please print) Signature of Second Parent/Guardian

Date: _____

For use with Authorized Representative Signature (other than parent/guardian as listed above):

For subjects unable to give authorization, the authorization is given by the following authorized subject representative:

_____ _____

Name of Authorized Subject Representative (please print) Signature

Date: _____

Provide a brief description of above person's authority to serve as the subject's authorized representative:

_____

_____