THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH

Melanoma Tissue Bank
LAB00-063

Subtitle: Template Update - Consent for blood and residual sample

Study Chair: Jeffrey E. Gershenwald

Jeffrey Bodin _____ 744652 _____

Participant's Name Medical Record Number

This consent and authorization form explains why this research study is being done and what your role will be if you choose to take part. You may choose not to take part in this study.

1. DESCRIPTION OF STUDY

The goal of this laboratory study is to collect blood and tissue to help researchers understand how patients respond to therapy, and help researchers learn why some patients respond differently, or do not respond to treatment.

This is an investigational study. Up to 10,500 patients will take part in this study. All patients will be enrolled at MD Anderson.

2. STUDY PROCEDURES

If you agree to take part in this study, you will have extra blood and tissue collected during a routine procedure. These samples will be stored in a research bank at MD Anderson for use in future research related to cancer. The tissue collected may be used for molecular and genetic studies of your melanoma, precursor lesions (lesions at risk for developing into melanoma or other types of skin cancer), and associated cutaneous pathology (other skin cancers or other lesions for which it is unknown if they may

develop into cancer) over time in order to understand how the cancer may get worse and/or how it may respond to treatments.

Data will be collected and may be stored in permanent restricted access controlled databases, where researchers must apply and be approved to access data. These databases include MD Anderson Melanoma Center and Department of Surgical Oncology databases, Institutional Data Repositories (IDR) such as the Big Data database, and a federal government, public, restricted database of Genotypes and Phenotypes also known as dbGAP. Both deposition of and access to data require governance and approval and will only contain non-identifiable data i.e., MD Anderson will not include research records in your medical records.

Your data and some of your genetic and health information may be placed into one or more of these restricted databases.

Your samples will be given a code number. No identifying information will be directly linked to your samples. Only the researcher in charge of the bank will have access to the code numbers and be able to link the samples to you. This is to allow medical data related to the samples to be updated as needed.

Before your samples or data can be used for research, the researchers must get approval from the Institutional Review Board (IRB) of MD Anderson through the use of institutionally approved protocols. The IRB is a committee of doctors, researchers, and community members. The IRB is responsible for protecting study participants and making sure all research is safe and ethical.

Blood Draws

Extra blood (about 10 tablespoons each time) will be drawn when your doctor orders blood to be drawn for routine tests during your treatment and follow-up care, for as long as you are being followed at MD Anderson.

If your doctor does not order a routine blood draw during your clinic visit, you may have an extra blood drawn for this study during that visit. You may have your blood drawn at any or all routine follow-ups or future treatment visits.

While you are taking part in this study, if at any time you are not feeling very well for any reason, you may tell the study doctor you do not want to have blood drawn during that visit. If you decide you do not want to allow blood to be drawn during a visit because you don't feel well, you will still be allowed to continue your participation in this study and blood will continue to be drawn at your next visit.

Tissue Collection

If you are having a routine biopsy and/or surgery, extra tissue will be removed at the time of your procedure. A small amount of normal skin may also be obtained that is around the tumor and/or lesion area.

Other Sample Collection
Other samples, such as saliva, fluid from around your spine, lung, and/or abdomen, and other bodily fluids, may be collected from existing drains or during planned procedures. Cheek or skin swabs and/or stool samples may also be collected during a routine visit. For the cheek swab, a small sample of cells from the inside of your mouth will be collected by scraping a cotton swab against the inside of your cheek a few times, until enough cells are collected.

Outside Sample Collection
If you have been seen at a facility outside of MD Anderson and have diagnostic or research samples stored with that facility, researchers may ask for permission to obtain those samples for this study. You will be asked to complete a special form to allow your samples to be released from the outside facility, to be stored as part of this study for future melanoma, precursor lesions, and/or associated cutaneous pathology research.

Sample Sent to Outside Facilities for Processing
Samples from this study may be sent to institutions outside MD Anderson, including The Wistar Institute, for additional research, including using samples from this study to create cell lines in animals (xenografts). Samples sent outside of MD Anderson will be de-identified and will not have any PHI sent with them.

Follow-Up
About 1 time a year after your diagnosis and treatment, during a routine follow-up visit or by phone, you will be asked about your general health, if you have had any health problems related to the melanoma, precursor lesions, and/or associated cutaneous pathology, if you have been diagnosed with a new primary disease or if the melanoma, precursor lesions, and/or associated cutaneous pathology has come back or spread. The phone call will take about 10 minutes.

Length of Study
You will be off study after your follow-up treatment and long-term information follow-up at MD Anderson is complete.

You may request to be taken off study at any time. If you ask to no longer be part of this study, you will not be asked to provide any samples in the future. Samples and information that have already been collected about you will still be available for research.

If you no longer wish to have your samples or information used for research, you may request to have the samples and information destroyed.

3. POSSIBLE RISKS

While on this study, you are at risk for side effects. You should discuss these with the study doctor. The known side effects are listed in this form, but they will vary from person to person.

Blood draws may cause pain, bleeding, and/or bruising. You may faint and/or develop an infection with redness and irritation of the vein at the site where blood is drawn. Frequent blood collection may cause anemia (low red blood cell count), which may create a need for blood transfusions.

Having **biopsies** performed may cause pain, bruising, bleeding, redness, low blood pressure, swelling, and/or infection at the site of the biopsies. An allergic reaction to the anesthetic may occur. A scar may form at the biopsy site.

Although every effort will be made to keep study data safe, there is a chance that your personal health information could be lost or stolen. All study data be stored in password-protected computers and/or locked file cabinets. There will be no personal identifying information connected to your questionnaire answers. The study data will be not be destroyed, but will be maintained on secured, password-protected, encrypted computers.

MD Anderson and others can learn about cancer and other diseases from your **banked samples**. In the future, people who may do research with these samples may need to know more information about your health. This information may be collected from your medical record. MD Anderson will make reasonable efforts to preserve your privacy, but cannot guarantee complete privacy.

Only authorized researchers may deposit or access the data from research with these samples. All samples will be given a code number and not directly linked to identifying information.

Sometimes your samples may be used for genetic research about diseases that are passed on in families. Genetic research may result in the development of beneficial treatments, devices, new drugs, or patentable procedures. If this happens, there are no plans to compensate you. MD Anderson will not be able to give you, your family, or your doctor the reports about the research done with these samples, and these reports will not be put in your medical record. If this information were released, it could be misused.

Such misuse could be distressing, and it could cause you or your family members to have difficulty getting insurance coverage and/or a job.

If you withdraw your consent to the storage of leftover samples in the tissue bank, then they will no longer be collected for storage. Any of your samples that remain in the tissue bank will no longer be used for research and will be destroyed.

However, if any of your de-identified samples was already released for research purposes before you withdrew consent, MD Anderson will not be able to destroy it.

This study may involve unpredictable risks to the participants.

4. POTENTIAL BENEFITS

Future patients may benefit from what is learned. There are no benefits for you in this study.

5. OTHER PROCEDURES OR TREATMENT OPTIONS

You may choose not to take part in this study.

6. STUDY COSTS AND COMPENSATION

If you suffer injury as a direct result of taking part in this study, MD Anderson health providers will provide medical care. However, this medical care will be billed to your insurance provider or you in the ordinary manner. You will not be reimbursed for expenses or compensated financially by MD Anderson for this injury. You may also contact the Chair of MD Anderson's IRB at 713-792-2933 with questions about study-related injuries. By signing this consent form, you are not giving up any of your legal rights.

There are no plans to compensate you for any patents or discoveries that may result from your participation in this research.

You will receive no compensation for taking part in this study.

ADDITIONAL INFORMATION

7. You may ask the study chair (Dr. Jeffrey E. Gershenwald, at 713-792-6940) any questions you have about this study. You may also contact the Chair of MD Anderson's Institutional Review Board (IRB - a committee that reviews research studies) at 713-792-2933 with any questions that have to do with this study or your rights as a study participant.

8. Your participation in this research study is strictly voluntary. You may choose not to take part in this study without any penalty or loss of benefits to which you are otherwise entitled. You may also withdraw from participation in this study at any time without any penalty or loss of benefits. If you withdraw from this study, you can still choose to be treated at MD Anderson.

9. This study or your participation in it may be changed or stopped at any time by the study chair or the IRB of MD Anderson.

10. MD Anderson may benefit from your participation and/or what is learned in this study.

Authorization for Use and Disclosure of Protected Health Information (PHI):

A. During the course of this study, MD Anderson will be collecting and using PHI, including identifying information, information from your medical record, and study results. For legal, ethical, research, and safety related reasons, your doctor and the research team may share your PHI with:

- Federal agencies that require reporting of clinical study data (such as the FDA, National Cancer Institute [NCI], and OHRP)
- The IRB and officials of MD Anderson
- Study monitors and auditors who verify the accuracy of the information
- Individuals who put all the study information together in report form

Study sponsors and/or supporters receive limited amounts of PHI. They may also view additional PHI in study records during the monitoring process. MD Anderson's contracts require sponsors/supporters to protect this information and limit how they may use it.

Dr. Jeffrey Gershenwald will receive study materials.

B. Signing this consent and authorization form is optional, but you cannot take part in this study if you do not agree and sign.

C. MD Anderson will keep your PHI confidential when possible (according to state and federal law). However, in some situations, the FDA could be required to reveal the names of participants.

Once disclosed outside of MD Anderson, federal privacy laws may no longer protect your PHI.

D. The permission to use your PHI will continue indefinitely unless you withdraw your authorization in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP) or you may contact the Chief Privacy Officer of MD Anderson at 713-745-6636. If you withdraw your authorization, the data collected up to that point can be used and included in the data analysis, but no further information about you will be collected.

CONSENT/AUTHORIZATION
(Adult Participants Only)

I understand the information in this consent form. I have had a chance to read the consent form for this study, or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

Jeffrey Bodin — 2/10/2019

SIGNATURE OF PARTICIPANT — DATE

LEGALLY AUTHORIZED REPRESENTATIVE (LAR)

The following signature line should only be filled out when the participant does not have the capacity to legally consent to take part in the study and/or sign this document on his or her own behalf.

SIGNATURE OF LAR — DATE

RELATIONSHIP TO PARTICIPANT

WITNESS TO CONSENT

I was present during the explanation of the research to be performed under Protocol **LAB00-063**.

SIGNATURE OF WITNESS TO THE VERBAL CONSENT PRESENTATION (OTHER THAN PHYSICIAN OR STUDY CHAIR) — DATE

A witness signature is only required for vulnerable adult participants. If witnessing the assent of a pediatric participant, leave this line blank and sign on the witness to assent page instead.

PERSON OBTAINING CONSENT

I have discussed this research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

Eliza Posada (234463) 2-8-19

SIGNATURE OF STUDY CHAIR
OR PERSON AUTHORIZED TO OBTAIN CONSENT

DATE

PARENT/GUARDIAN PERMISSION

I have read and understand the description of this research. I have had a chance to discuss the study and ask questions. My questions have been answered. I give permission for my child or ward to take part in this study.

SIGNATURE OF PARENT/GUARDIAN _____ DATE _____

SIGNATURE OF PARENT/GUARDIAN _____ DATE _____
Signature of Other Parent (Optional, unless required by the IRB.)

___ The IRB has determined that the signature of both parents is required.

If not obtaining both parental signatures, please indicate reason below:

___ Other parent is deceased, unknown, incompetent, or not reasonably available.

___ Parent/Guardian signing above has sole legal responsibility for the care and custody of the child.

X The IRB has determined that the signature of both parents is NOT required.

___

WITNESS TO PARENTAL/GUARDIAN PERMISSION

I was present during the explanation of the research to be performed under Protocol **LAB00-063**. The child participant was also present. In my opinion, the parent(s)/guardian provided permission for the child to participate in the research.

SIGNATURE OF WITNESS TO THE PARENTAL/GUARDIAN PERMISSION (OTHER THAN PARENT/GUARDIAN OR MEMBER OF THE STUDY TEAM) _____ DATE _____

ASSENT OF MINOR

(Entire section must be completed if the participant's intellectual age is at least 7 and less than 18 years. Participants with an intellectual age of 7 - 12 are not required to sign.)

If written assent is not obtained on an age-appropriate participant, check reason why not:

____ 1.) The participant's intellectual age is less than seven.
____ 2.) The participant dissented, but the participant's parent(s)/guardian felt that the intervention(s) or procedure(s) involved in the research hold out the possibility of a direct benefit that is important to the health and/or well being of the participant and is available only in the context of this research study.
____ 3.) Other: _____

I have been told what I will be asked to do in this study.

I have been told that I do not have to be in this study. If I decide not to be in this study, no one will be mad at me. I may quit at any time, but if I do, I may need to take a different treatment.

I have had a chance to talk about the study and ask the study doctor questions. All of my questions have been answered. I agree to be in this study and do what I am asked to do so long as I want to stay in this study. I agree that the study doctor can put me on this study. By signing this paper, I am not giving up any of my legal rights. I have been given a copy of this document.

_____ _____
SIGNATURE OF MINOR (Age 13-17) DATE

WITNESS TO ASSENT
I was present during the explanation of the research to be performed under Protocol **LAB00-063**. The child participant was also present. In my opinion, the child assented to participate in the research. (Note: If obtaining assent, a witness signature is required.)

_____ _____
SIGNATURE OF WITNESS TO THE ASSENT (OTHER THAN PARENT/GUARDIAN OR MEMBER OF THE STUDY TEAM) DATE

TRANSLATOR

I have translated the above informed consent as written (without additions or subtractions) into _____ and assisted the people
(Name of Language)
obtaining and providing consent by translating all questions and responses during the consent process for this participant.

NAME OF TRANSLATOR	SIGNATURE OF TRANSLATOR	DATE

☐ Please check here if the translator was a member of the research team. (If checked, a witness, other than the translator, must sign the witness line below.)

SIGNATURE OF WITNESS TO THE VERBAL TRANSLATION (OTHER THAN TRANSLATOR, PARENT/GUARDIAN, OR STUDY CHAIR)	DATE