# Information and Consent Form

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| **Study Title:** | Melanoma Research Alliance Biorepository for Patients with Melanoma |
| **Sponsor:** | Melanoma Research Alliance |
| **Protocol Number:** | v2.0 |
| **Principal Investigator:** | Joan Levy, PhD |
| **Email:** | jlevy@curemelanoma.org |
| **Address:** | 730 15th St NW Washington, DC 20005 |

**Key Information You Should Know Before Agreeing to Participate:**

The key information will help you learn more about this cancer research project. It can help you decide whether or not to take part in the study**. Please read the entire consent form or have someone read it with you.** If you are thinking about volunteering, please take as much time as you need to read this form, ask questions of our staff and your doctor, discuss this project with anyone, before volunteering to be part of it.

1. **Voluntary Participation and Right to Discontinue Participation:**
   - We are asking your permission, also called consent, to include you in a cancer research project called the Melanoma Research Alliance (MRA) Biorepository for Patients with Melanoma that is being run through or sponsored by the MRA. Your participation is voluntary and should be based on what is important to you and your comfort to be included. It is your choice to participate in this study. If you agree to participate, you may leave at any time without penalty or loss of benefits to which you are otherwise entitled.
2. **Purpose of the Research:**
   - The purpose of MRA Melanoma Biorepository research study is to collect and store melanoma tissue and normal tissues from patients with different types of melanomas and with a certain amount of associated health information. The samples and information can be later used in research studies to identify better treatments and ways to manage the disease.
3. **Expected procedures to be followed:**
   - Your procedure such as a biopsy, surgery or fluid tap is part of your medical treatment plan agreed to with your doctor and not part of this research project. We are asking your permission to collect the excess melanoma tissue that may be stored or thrown away that is not needed for any medical evaluations.
   - We also may need normal tissue from your body to make comparisons with your melanoma tissue. This can be obtained from small amounts of normal tissue removed with the tumor tissue, excess blood collected that is not needed for your normal care, a new tube of blood that we can arrange having drawn, or by swabbing the inside of your cheeks or collecting your saliva.
   - We will also ask you for certain health information (age, ethnicity, diagnosis, medical treatments, etc.) that is important to associate with your samples. If you are a participant in the MRA RARE registry, your registry data will be linked to any donated specimen.
4. **Appropriate alternative procedures:**
   - The study does not involve any treatments for your melanoma. Your alternative is to not participate in this research project, and it will not affect your clinical care in any way.

5. **Key reasonably foreseeable risks and discomforts:**
   - If an additional tube of blood is needed there may be side effects from drawing a blood sample including mild pain, bleeding, bruising or an infection at the site of the needle insertion.
   - We undertake safety measures to keep your personal information confidential. However, some of the information may still be traceable to you and we cannot guarantee that your identity will never become known.
6. **Reasonably expected benefits:**
   - You may not benefit directly from taking part in this project. This research may only give us knowledge that will help melanoma cancer patients in the future.
7. **Compensation and costs related to your participation:**
   - You will not be paid to participate in this research study, and it will not cost you anything to participate.

**There is much more detailed information below that you should carefully read before signing this consent.**

## A. Purpose of the MRA Melanoma Biorepository:

A biorepository (also referred to as a "biobank") collects human biological samples, such as blood, tissue (normal and cancerous), or body fluids and associated health information. Samples from many people are stored so they can be used by researchers for projects now and in the future.

The purpose of MRA Melanoma Biorepository is to collect and store melanoma tissue from patients with different types of melanomas. This includes the more common type of melanoma, called cutaneous melanoma, and some of the other rare sub-types including but not limited to acral and mucosal melanomas. In some cases, blood and/or other normal tissue may be collected for comparison to the melanoma tissue. The tissue will be used for research purposes to study the different types of melanomas, to identify better treatments and improve outcomes for melanoma patients. The tissue is most useful when it is connected to health data from the tissue donor, which includes information such as how the disease was diagnosed, treatments received, and responses to the treatment. However, scientists carrying out the research will not know the identities of individuals who donate tissue.

### *A1. Background Information.*

Research has shown that there are many types of differences between normal cells and cells that become cancerous, like melanoma. For instance, tissues in your body are made up of cells that contain DNA. DNA is the material that provides a code of instructions that tell your body's cells how to develop and function. Changes in this code can lead to cancer, a disease in which cells stop following their normal biological instructions and begin to grow out of control. There are other changes in cancer cells that have been identified that lead to their uncontrolled growth and ability to spread to other tissues however, there is still a need to learn more. The cancer and normal tissues donated to the MRA Melanoma Biorepository can help identify additional information that might lead to new treatments and better ways to understand why some patients respond to certain treatments and others do not. In addition, if the project successfully isolates immune cells from the tissue samples,

researchers can study ways in which the body may promote its immune defense against cancer.

In addition to analyzing the cancer tissue directly, cells can be isolated from tumor tissue and grown in plastic dishes (cell culture) and grown in animals. These 'models' can be useful to scientists who want to understand how melanoma is caused and can grow and spread. These models also can be used to test the sensitivity of cancer cells to existing drugs and to develop new drugs.

To study melanoma, researchers will take some leftover tissue from your tests, surgery, or fluid taps. This is tissue that otherwise would likely be discarded. Some samples of the tissue will also be saved for future research as we learn more about the disease.

### *A.2. Why are we asking you to volunteer for this project?*

You have had a clinical exam that identified tissue growth that may be cancerous. Or you may already have been diagnosed with a type of melanoma. You are being asked to participate in this project because, as part of your melanoma cancer care, you have had or are having: 1) your growth biopsied; 2) are undergoing surgery to have your tumor removed; or 3) a tap to remove fluid that is likely to contain cancer cells. Normally, any extra tissue obtained from this process that is not required for your medical care may be discarded. This extra tissue may include melanoma cells and some nearby non-melanoma cells, which could be used for research. We are requesting your permission to use some of that extra melanoma tumor tissue (and available normal tissue), and to collect information from your medical records to study your cancer and/or to try to build a model (cultured tumor cells grown in plastic dishes call tumor cell lines and/or tumor cells grown in animals) of your melanoma. We will save any remaining tissue for later use. The following sections describe how your tissue samples and information will be collected and studied if you give us this permission.

### *A3. Project results.*

Results obtained in this research project on your individual cancer will not be given back to you, your doctors, or put into your medical records. This project is focused on using your sample(s) for specific research studies that have been reviewed and approved by the MRA and a special committee of expert melanoma scientists and clinicians who are knowledgeable of this type of research.

### *A4. Re-contact and return of research results.*

We may periodically re-contact you with general information about upcoming research opportunities or to distribute educational materials relating to the Melanoma Research Alliance and/or the biorepository.

In the future, MRA might choose to return individual research results to interested participants. However, at this time the sponsor will share only general summarized research developments on its public website, or a designated data portal or through scientific publications. If there is an opportunity to return your individual research results, you would be recontacted and then asked to sign a new consent to obtain the results.

## B. Protecting your Privacy and Keeping your Information Confidential.

We will work very hard to keep your information confidential.

If you volunteer to be part of the project, this signed consent form will either be stored in a locked file (if you are signing a paper consent), or in a secured computer system (if you are signing an online consent).

Results of this research project may be reported in medical journals or at scientific meetings. However, the people who consented to donate their samples and medical information will not be named.

### *B1. Removing your identity from your tissue samples and medical information.*

Your tissues and medical information will be de-identified, which means that all your obvious identifiers (such as name, medical record number, address, and phone number) will be stripped away. Your samples and information will be labeled only with a random number code.

If a model derived from your tumor (such as a tumor cell culture line or tumors grown in animals) is created, the link between the model and your identifiable information will be permanently broken after the model is successfully created and a given set of information has been collected. This will occur prior to the storage of the model in any repository. Therefore, the model created from your samples will not be linked back to you.

## C. Your Samples and Medical Information.

### *C1. How will my samples and medical information be collected?*

Your procedure, such as a biopsy, surgery, or fluid tap, is part of a medical treatment that you agreed upon with your doctor. That procedure is not part of this research project. During the procedure, cancer tissue was or will be removed. Often more tissue is removed than is needed to diagnose your cancer or to assess your response to therapy. The excess tissue may be stored or thrown away. After the Pathology Department takes the tissue they need for your medical care, we are asking your permission to collect the excess cancer tissue.

We would like to have a source of normal cells from your body to make comparisons with your cancer or melanoma cells. This may allow researchers to understand what causes melanoma and how it can be treated. To do this, we can analyze normal cells from a blood sample that will already have been collected as part of your routine care. Many times, more blood is collected than is needed for your clinical care, and the unused portion is usually thrown away or stored. We are asking your permission to use some of that extra blood for analysis. It may be necessary to collect a tube of blood, so we are also asking your permission to arrange drawing blood from a vein in your arm. As an alternative, we can collect some normal cells by swabbing the inside of your cheeks or collecting saliva.

We are also asking to collect health information about you including your age, ethnic background, diagnosis, disease history, medical treatments, biomarker analysis, and response to treatments. We may ask you for additional health information which is included in your medical reports such as pathology and surgical reports as some examples. You may also be contacted by MRA at different times to be asked additional questions regarding your medical information. You can decide what

information you would like to share, and it will not affect your participation in the study.

If you are also a participant in the MRA RARE registry initiative, information obtained through the registry will be linked to your donated samples. Inclusion in the RARE registry does not require inclusion in the biorepository and vice versa.

You may decline any request for a specimen that you do not want to provide. If you die and have an autopsy, we may request sample collection. Your family would need to provide consent for such collection at that time.

### *C2. How will my samples be used by researchers?*

Your samples may be used immediately or stored indefinitely for future use. Tissue may be used directly by cancer researchers, and/or they may be given the opportunity to create cancer models from the tissue. Researchers may study cancer cells and/or other cells in the tissue, such as those of the immune system. Blood and other donated fluids could be used to discover biomarkers of the disease to predict the likelihood of responding to therapy or being resistant to treatments. All researchers will have an approved protocol from their institution to use and study this tissue and will not have access to any identifiable information about you. Any research study using your samples must also be approved by a Tissue Use Committee of leading experts in the field of melanoma research appointed by the MRA. In addition, researchers must agree not to attempt to identify you from any information that they obtain from your samples.

### *C3. How will my health information be used and shared?*

This section explains who will use and share your health information if you agree to participate in this biorepository. If you do not authorize this use and sharing of your information by signing this form, or if you cancel this authorization later, you may not be able to participate in the biorepository.

The MRA and people or consultants who work with or for MRA will collect and use health information about you needed for their records, including identifying information, such as your name, address, phone number, email, etc. They will also collect additional information from any medical reports (ie. pathology, surgical) that you provide to us.

Federal Privacy Regulations provide safeguards for privacy, security, and authorized access of participant data. In the circumstances listed below, MRA may be legally required to share your protected health information (which means information that can individually identify you) with federal and state agencies or shared with other people in the following situations:

- The sponsor, Melanoma Research Alliance, and people who work with or for the sponsor will use your records to review the study and to check the results of the study.
- The biorepository staff or companies working for the biorepository, to collect the samples for the biorepository and to maintain and share the samples.
- Representatives from the US Department of Defense, which is funding parts of this study, may have access to your private health information during monitoring activities for compliance purposes as well as other government agencies in the US and other countries, and North Star Review Board.
- You release your information to other people not involved in the study.

- You agree in writing to the release of your information to other people

Your authorization on this form does not have an expiration date. You can cancel your authorization to use and share information that identifies you at any time by emailing your request to the biorepository staff member on page 1 of this form or biorepository@curemelanoma.org. Even if you cancel your authorization, any information that has already been given out to researchers and any information that was already de-identified may continue to be used.

Your protected health information will be stored in a different database from your medical, non-identifiable information. Only authorized employees or consultants of MRA who have received special training and are certified in protecting human participant data, and you and your caregiver will have access to your protected health information.

Information from analyzing your samples or models made from the samples will be put into a central database for researchers, along with information from the other people with melanoma who volunteered for this project. Associated with the samples will be the health/medical information that you provided that will have all identifiable information removed. If you are a participant of the RARE registry, information in the surveys you filled out and medical reports/records that you consented for MRA to abstract additional information will also be associated with your samples in this central database for researchers. To access the database, any researcher will have to agree to: 1) use the data only for research projects; and 2) never use the data to identify the donors of the specimens/samples.

### *C4. Connecting your information to other studies you are participating in including the MRA RARE registry.*

You may be a participant in another study that the MRA is leading called the MRA RARE registry. MRA will already know your identity and will be able to associate information collected from you in the RARE registry with the information collected on your samples and associated health information from this biorepository study. If you do not want information shared between the two research studies, please contact the biorepository by emailing biorepository@curemelanoma.org.

Your samples and identifying information *may* be shared with other studies in which you are participating. Such investigators will already know your identity and will be able to associate information they have collected in their studies with samples and information from the MRA Biorepository. The biorepository will share information with such researchers if they can demonstrate that you have given consent to participate in their study. **If you do not want your information shared between the biorepository and other studies to which you have explicitly given your consent to participate, please contact the biobank by emailing biorepository@curemelanoma.org.**

## D. Potential Risks of Participating in this Project.

There are some risks if you decide to participate in this research project.

### *D1. Blood draw risks.*

There are very few risks associated with this project. In the event that an additional tube of blood

needs to be drawn, there are possible side effects from drawing a blood sample. These include mild pain, bleeding, or bruising. Sometimes an infection can happen at the site of the needle insertion. Fainting or light-headedness can sometimes occur, but usually lasts only a few minutes.

### *D2. Risks if information about you is accidentally released.*

Keeping your personal information confidential is very important to us and we use many safety measures to protect that information. However, some of this information may still be traceable to you and we cannot guarantee that your identity will never become known. It is possible, for example, that there could be violations to the security of the computer systems used to store the link between the random number code of your samples and health information to your name or other identifiers. It is also possible that, in the future, someone could compare information in our databases with information from you (or a relative) in another database and be able to identify you (or your relative).

While we believe the risks to you and your family of disclosure of your private information are low, we are unable to tell you exactly what all the risks are. There are some laws that protect you against genetic discrimination by employers or insurance companies. In 2008 the Federal government passed the Genetic Information Nondiscrimination Act (GINA), a law that prohibits genetic discrimination in employment and health insurance. It is important to note that while this law protects you from certain kinds of genetic discrimination, there are exceptions. For example, GINA does not apply to employers with fewer than 15 employees. Additionally, this law does not protect you from genetic discrimination in life, disability, or long-term care insurance.

If your identity became known, here are some of the possible risks:

- There could be psychological or social risks associated with loss of privacy. For example, your genetic information could potentially be used in ways that could cause you or your family distress by revealing that you (or a relative) carry a genetic disease. This could lead to the denial of life insurance for you (or a relative).
- The genetic information from your samples and from the cancer model may be obtained by a method called sequencing. Sequencing allows researchers to read the codes of instructions that are spelled out in your DNA and helps them identify genetic changes that contribute to the cancer process. There is the possibility that your genetic information may be used to identify you and your family members since relatives share genetic information. Patterns of genetic variation also can be used by law enforcement agencies to identify you or your relatives.
- There may also be other privacy risks that we have not foreseen.

## E. Voluntary Participation.

### *E1. What if I work for the sponsor of this study? What if I am a family member of someone who works for the sponsor?*

Sponsor employees and their family members do not have to be in this study. An employee's or his/her family member's decision to be in the study, or to leave the study early, will not affect the employee's job or job benefits.

### *E2. Benefits of participating in this study.*

It is likely that you will not personally benefit from this project because the research is still in its early stages.
The main reason you may want to participate is to help researchers and health professionals around the world to better understand the causes of melanoma and other cancers so that they can find better ways to prevent, detect, treat, and cure them in the future.

### *E3. Who is paying for the study?*

The MRA, the sponsor of this study, is paying for this study in part with funding from the United States Department of Defense office of the Congressionally Directed Medical Research Program through a grant to the MRA supporting the development of a biorepository of samples from 300 patients with acral melanoma. The MRA uses its general funds and also accepts funding from third party sources to help underwrite the remaining portions of the MRA Melanoma Biorepository.

### *E4. Costs and payments to you.*

It will not cost you anything to participate in this project.

You will not be paid to participate in this project.

Your medical information, tissue samples, and any models that are made will only be used for research. However, it is possible that some of the research using your samples could eventually lead to the invention of new diagnostic tests, new drugs, or other products that could be sold by companies. If this happens, you will not get any part of the profits from these products.

### *E5. Withdrawing from the project.*

You may choose to stop being part of this research project for any reason. What your withdrawal will mean will depend on certain criteria as described below:

- Your donated specimens may be used: 1) to investigate how different types of melanoma progress; 2) to understand how melanoma can respond to different drugs and treatments; 3) to create research models; or 4) to identify biomarkers that may make the disease easier to diagnose at early stages. If you wish to withdraw from this study and have your samples removed from the biorepository, specimens can be destroyed immediately along with accompanying medical data associated with it. We will notify researchers to whom the specimens may have been distributed to also discard their aliquots of your samples and data

but cannot guarantee that they will be destroyed. MRA cannot retract research data from analysis of your samples that have already been published.

- If you withdraw after we have created a research model from your tissue specimen and have collected the necessary information, and that model has been deposited into a public repository, it will no longer be possible to discard your samples or the model, or to remove your information. This means that if you agree to let us use your tissues and information, and cancer models are successfully grown from your samples, the models and your associated information could be used forever.
- If you choose not to participate or to withdraw from the study later, it will not affect your present or future medical care, and it will not cause any penalty or loss of benefits to which you are otherwise entitled.

To withdraw from this study, please contact the research staff of the Melanoma Research Alliance at biorepository@curemelanoma.org.

### *E6. Alternatives to participating in the study.*

This study (project) does not involve any treatment for your melanoma. Your alternative is to not participate in this biorepository project.

## F. Agreeing to Participate in the Project.

Cogswell Consulting LLC has been hired by MRA as consultants to assist in the consent process and make arrangements to have your samples sent to the MRA Melanoma Biorepository. You will be given a copy of this consent form in case you want to read it again. You can contact MRA and Cogswell Consulting for consent related questions at the following email address: biorepository@curemelanoma.org. Please note that the Principal Investigator of the study, Dr. Joan Levy, remains responsible for all aspects of study conduct.

### *F1. Whom to contact about this study.*

During the study, if you experience medical problems related to this study, suffer a research-related injury, or have questions, concerns, or complaints about the study, please contact the Investigator at the email address listed on the first page of this consent document or email biorepository@curemelanoma.org. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An Institutional Review Board (IRB) has reviewed this Biorepository proposal and consent to ensure that it meets ethical and regulatory standards for protecting your rights. An IRB is an independent group that reviews research proposals to make sure they properly protect participants. For questions about those protections and your rights as a participant in this Biorepository, or to discuss other related concerns or complaints with someone who is not part of this Biorepository team, please contact North Star Review Board at 877-673-8439 (toll free) or info@northstarreviewboard.org. You may want to contact the IRB if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research participant.

Please do not sign this form unless you have had all your questions answered.

**DOCUMENTATION OF CONSENT**

My signature below indicates:

- I have had enough time to read the consent form and think about participating in this study;
- I have had all my questions answered to my satisfaction;
- I am willing to participate in this study;
- I have been told that my participation is voluntary, and I can withdraw at any time;
- I agree to allow the collection, use and sharing of my samples and information as described above;
- I am willing to be contacted in the future for follow-up interviews about my health information, to obtain future samples, or to learn about new research opportunities.

By signing this form, I do not give up any of my legal rights. I will receive a fully signed copy of this consent form.

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| Name of Participant | Date of Birth |
| Signature of Participant | Date |

I attest that the participant or other individual providing consent had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to be in this project.

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| Printed Name of Person Explaining Consent | |
| Signature of Person Explaining Consent | Date |