

OHSU Knight Cancer Institute Information Sheet

TITLE: War on Melanoma: Enlisting a cohort of melanoma survivors and their families

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“You” refers to you or your child in this consent form.

This is a registry, a type of research database. Research registries include only people who choose to take part. Please take your time to make your decision. You can discuss your decision with your friends and family. You can also discuss it with your health care team. If you have any questions, ask the investigator.

You are invited to take part in this registry because you are interested in melanoma research, have been identified as someone who has a personal history of melanoma or are a relative or friend of someone who had melanoma, or are using the Mole Mapper Study cellphone application.

WHY IS THIS STUDY BEING DONE?

You are invited to join a registry of melanoma patients, their families and friends. The Melanoma Community Registry will serve as a resource for communicating with you about future melanoma community outreach projects and research that may be of interest to you. By agreeing to be included in the Melanoma Community Registry, you are providing consent or permission for OHSU researchers to keep information you provide to the Melanoma Community Registry in a confidential, privacy-protected, ethics board-approved database. You are authorizing them to contact you in the future regarding other melanoma educational and community events, free skin cancer screenings, and/or skin cancer research opportunities. Your participation in any of these events is completely voluntary and you can request removal from the registry at any time.

HOW MANY PEOPLE WILL TAKE PART IN THIS REGISTRY?

As many as 100,000 people will take part in this registry, which will be managed by Oregon Health & Science University.



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WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH REGISTRY?

The information you choose to provide will help researchers learn about melanoma. The amount of information you provide the registry is up to you. In addition to your contact information, OHSU may ask you to fill out optional questionnaires and provide other information about your health. All data included in the Melanoma Community Registry will be stored in a secure database maintained by OHSU. With your permission, researchers from OHSU may also access information about you stored in other databases (e.g. data collected through the Mole Mapper App research collaboration between OHSU and Sage Bionetworks).

Researchers outside of OHSU may ask the Department of Dermatology to contact you about research studies they are conducting. In this case, OHSU researchers will contact you on their behalf (the researchers will not be given your contact information unless you directly provide it to them) so that you can decide if you'd like to participate in that future research. If you decide you do want to participate you will be given the information necessary to contact the researchers directly. Only studies relevant to melanoma, approved by an ethics board, and reviewed by the OHSU study team will be eligible to use this registry for research.

Before you agree to participate in any future research, the investigator must tell you:

1. Why the research is being done, what you will have to do, and how long it will last;
2. The risks and benefits of the research;
3. What other choices you have if you prefer not to join the research study; and,
4. How information about you will be protected.

Depending on the study, the investigator may also tell you about:

1. What will happen if you are harmed by the study;
2. What happens if you decide to stop participating in the study;
3. New risks that may be discovered during the study;
4. The reason(s) why you may be asked to leave the study before it is completed;
5. Costs, if any, you may be responsible for; and
6. How many people will be in the study.

HOW LONG WILL I BE IN THE REGISTRY?

Your information will be stored indefinitely, unless you request to be removed from the registry.

WHAT ABOUT COMMERCIAL DEVELOPMENT?

Information provided, including any survey responses, photographs, videotapes, or audiotapes about you or obtained from you as part of the Melanoma Community Registry, may be used for commercial purposes, such as making a discovery that could, in the future, be patented or licensed to a company, which could result in a possible financial benefit to that company, OHSU, and its researchers. There are no plans to pay you if this happens. You will not have any property rights or ownership or financial interest in or arising from products or data that may result from your participation in this study. Further, you will have no responsibility or liability for any use that may be made of your samples or information.

WHAT RISKS CAN I EXPECT FROM BEING IN THE REGISTRY?

We take significant precautions to protect your information included in the Melanoma Community Registry. All of the information you provide to the Melanoma Community Registry is stored at OHSU on a secure, HIPAA-compliant server. However, there is a small risk of loss of confidentiality. If the information in this registry were to be accidentally released, it might be possible that the information we will gather about you as part of this registry could become available to others.

If you are injured or harmed while participating in the Melanoma Community Registry or while using the cellphone application for the Mole Mapper Study, you will be treated. OHSU does not offer any financial

compensation or payment for the cost of treatment if you are injured or harmed as a result of participating in this research. Therefore, any medical treatment you need may be billed to you or your insurance. However, you are not prevented from seeking to collect compensation for injury related to negligence on the part of those involved in the research. Oregon law (Oregon Tort Claims Act (ORS 30.260 through 30.300)) may limit the dollar amount that you may recover from OHSU or its caregivers and researchers for a claim relating to care or research at OHSU, and the time you have to bring a claim.

If you have questions on this subject, please call the OHSU Research Integrity Office at (503) 494-7887.

ARE THERE BENEFITS TO TAKING PART IN THE REGISTRY?

You may or may not personally benefit from being in this registry. However, by serving as a participant, you may help us learn how to benefit patients in the future.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT TAKE PART IN THIS REGISTRY?

You may choose not to be in this registry.

WILL MY INFORMATION BE KEPT PRIVATE?

We will take steps to keep your personal information confidential, but we cannot guarantee total privacy.

WHAT ARE THE COSTS OF TAKING PART IN THIS REGISTRY?

There will be no cost to you or your insurance company to participate in this registry.

WHAT ARE MY RIGHTS IF I TAKE PART IN THIS REGISTRY?

If you have any questions regarding your rights as a research participant, you may contact the OHSU Research Integrity Office at (503) 494-7887.

You do not have to join this or any research study. If you do join the registry and later change your mind, you have the right to withdraw at any time. This includes the right to withdraw your authorization to use and disclose your health information.

WHAT WILL HAPPEN IF I CHOOSE TO STOP PARTICIPATING IN THE REGISTRY?

You can decide to stop at any time. If, in the future, you decide you no longer want to participate in this registry, we will delete your information from the Melanoma Community Registry. However, if your information is already being used in an on-going research project and if its withdrawal jeopardizes the success of the entire project, we may continue to use it until the project is completed.

WHO CAN ANSWER MY QUESTIONS ABOUT THIS REGISTRY?

War on Melanoma staff at telephone: 1-844-300-SPOT (7768) is available to answer any questions you may have about this registry or you can email us at WarOnMelanoma@ohsu.edu.