



IRB#: 16038

Research Consent Summary

You are being asked to join a research study. You do not have to join the study. Even if you decide to join now, you can change your mind later.

1. The purpose of this study is to learn more about skin health and melanoma risks.
2. We want to:
 - a. Build a large resource of mole images and measurements
 - b. Better understand the dynamic variability in moles
 - c. Educate people on melanoma risk
3. This project is funded by the Department of Dermatology and the Knight Cancer Institute at Oregon Health & Science University (OHSU)
4. The project is ongoing and does not have a stated termination date.
5. Some survey questions may make you feel uncomfortable. There is a small risk of breach of confidentiality. Data collected in this study may use your phone's mobile data plan.
6. If you agree to participate, images and information collected during the study may be saved for future research.



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OHSU Knight Cancer Institute Consent and Authorization Form

TITLE: Mole Mapper

PRINCIPAL INVESTIGATOR: Sancy Leachman, MD, PhD (503) 494-8533

CO-INVESTIGATORS:

Pamela Cassidy, PhD	(503) 494-9047
Tracy Petrie, PhD	(503) 494-8410
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FUNDED BY: The Department of Dermatology and the Knight Cancer Institute at Oregon Health & Science University (OHSU)

PURPOSE:

You have been invited to be in this research study because you have expressed interest in using the Mole Mapper app to help with research. The purpose of this study is to build a large resource of mole images and measurements to better understand the dynamic variability in moles and to educate people on melanoma risk. The insights may help develop personalized interventions to detect melanoma early and reduce the incidence of disease.

This study is ongoing and of indefinite duration. You may withdraw from the study at any time, however the application will remain on your phone until you delete it. You can keep using the app to track your moles for as long as you like.

If you agree to participate, we will ask you to provide information related to your melanoma risk such as hair and eye color, mole images using the camera on your smart phone, information about those moles, and to optionally answer a few survey questions each month. You will also be enrolled in OHSU's melanoma data bank, War on Melanoma Registry (IRB 10561). These data will be stored indefinitely and may be used and disclosed in the future for research.

We will not restrict the number of participants in the study.

PROCEDURES:

If you decide to join the study you will need to download the free Mole Mapper application on your smart phone and register with the study. Then, we will ask you to answer a few

questions about yourself and take photographs of your moles using the Mole Mapper application and your mobile phone camera.

After you register with the study, you will be asked to answer a few questions about yourself such as your hair and eye color and jobs you have worked in. You may skip any question and the survey should take less than 5 minutes. The monthly questions should take less than one minute to answer. They may ask questions such as whether you have gotten a sunburn in the last month. You may also choose not to answer any of these questions.

We will send monthly reminders through the app asking you to re photograph your moles and answer a few questions. You may choose to act at your convenience, participate in all or only in some parts of the study. This study should take you about 20 minutes per month.

You may be asked to give us health information about your relatives. Any information you give us will be kept confidential as described in this consent. We will not contact your relatives.

As part of the War on Melanoma Registry you may be contacted via the email you provide and given the opportunity to participate in new research opportunities. If you elect to broadly release your data to through the Sage Bionetworks Synapse portal, your identifying information will be removed as described below. Your de-identified data will then be pooled with data from other participants and made available only to Qualified Researchers.

During this study your moles will be photographed. We may use the photographs for research publications, as long as they do not contain any identifying information or such information can be digitally obscured using black bars.

RISKS AND DISCOMFORTS:

There are risks, discomforts, and inconveniences associated with any research study. These deserve careful thought:

- This is not a medical treatment study. We do not expect any medical side effects from participating.
- Some survey questions may make you feel uncomfortable. Know that the information you provide is entirely up to you and you are free to skip questions that you do not want to answer.
- Other people may glimpse the study notifications and/or reminders on your phone and realize you are enrolled in this study. This can make some people feel self conscious.
- Accidental public disclosure may occur due to unintended data breaches including hacking or other activities outside of the procedures authorized by the study. In such a case, your data may be misused or used for unauthorized purposes.
- Data collected in this study will count against your existing mobile data plan. You may configure the application to only use WiFi connections to limit the impact this data collection has on your data plan.

Participation in this study may involve risks that are not known at this time. You will be told about any new information that might change your decision to be in this study.

BENEFITS:

The goal of this study is to create knowledge, which can benefit us as a society. We will publish the insights learned from analysis of the study data but these insights may not be of direct benefit to you. However, you will be able to track your moles and export your data at will to share with your medical doctor and anyone you choose.

ALTERNATIVES:

You may choose not to be in this study.

CONFIDENTIALITY:

We will take steps to keep your personal information confidential, but we cannot guarantee total privacy. This is a low risk because we separate and/or de-identify personal information that can directly identify you, such as your name or email from the study data to respect your privacy. Only the study organizers and some IT staff will have the key to associate your coded study data to your name and account information. However, certain skin features like tattoos or birthmarks may be unique to you and enable your re-identification despite our curation efforts (described below). So even though your name is kept separate from your coded study data, it is possible that someone could still figure out your identity. To reduce this risk, we recommend photographing moles at close range (~6 inches from skin surface) to minimize capture of secondary identifiable skin features.

Data de-identification

The Mole Mapper study data collected through the app will be encrypted on your phone, transferred electronically and stored securely in Synapse (synapse.org), Sage Bionetworks' data repository and analysis platform in the United States using secure Cloud services. We will separate your account information (name, email, contact information, etc.) from your study data (your responses to surveys and photographs of moles) to be analyzed.

We will use a random code number instead of your name on all your study data. This code cannot be used to directly identify you. Information about the code will be kept in a secure system. Only the study investigators, including War on Melanoma researchers and essential IT staff will have the key to link your coded study data to your name and account information.

We will NOT access other information on your smartphone for example, your personal contacts, other applications, text or email message content, or websites visited. We will never sell, rent, or lease your contact information.

Where will my data be stored?

Your study data (survey responses, photographs and measurements of moles) will be encrypted and transferred for data storage and analysis to Sage Bionetworks in the United States. We will combine your coded study data (without your name) with those of other study participants for analysis. For more information about Sage's data practices in the context of the Synapse research platform, see the Synapse Governance Overview [<https://www.synapse.org/#!/Wiki:syn2502577/ENTITY>]

How is my coded study data used in research?

Your study data (without your name) will be curated by members of the study team and added to the data of other study participants. Curation involves removing from the study data facial images, removing images that contain easily identifiable markings such as tattoos or birthmarks, verifying that they are useful (e.g. not too fuzzy and are pictures of

moles), and if applicable are accurately labeled. Individuals performing curation will be under the oversight of the Principal Investigator

This study gives you the option to share your coded study data broadly, with qualified researchers worldwide for use in this research and beyond to benefit future research both academic and commercial. If you choose to share your study data broadly, your coded unnamed metadata (your response to survey questions and the mole measurements without the mole photo) will be added to a shared dataset available to qualified researchers on the Sage Bionetworks Synapse servers. (www.synapse.org). Your mole photos will be available to qualified researchers who have received ethical approval to use the photos for their research. It is important to note that the Principal Investigator and Sponsor will have no oversight on the future use of the shared study data by other researchers.

We will create and collect health information about you as described in the Purpose and Procedures sections of this form. Health information is private and is protected under federal law and Oregon law. By agreeing to be in this study, you are giving permission (also called authorization) for us to use and disclose your health information as described in this form.

The investigators, study staff, and others at OHSU may use the information we collect and create about you in order to conduct and oversee this research study, store in a repository, and conduct future research.

We may release this information to others outside of OHSU who are involved in conducting or overseeing research, including:

- The Office for Human Research Protections, a federal agency that oversees research involving humans
- The National Cancer Institute (NCI)

Those listed above may also be permitted to review and copy your records.

We will not release information about you to others not listed above, unless required or permitted by law. We will not use your name or your identity for publication or publicity purposes, unless we have your special permission.

When we send specimens or information outside of OHSU, they may no longer be protected under federal or Oregon law. In this case, your specimens or information could be used and re-released without your permission.

Your authorization for the use and/or disclosure of your information will expire if you choose to withdraw from the research study subject to any time limitations imposed by applicable law or by December 31, 2060.

If you choose to withdraw from the research study, we will stop collecting your study data. At the end of the study period we will stop collecting your data, even if the app remains on your phone and you keep using it.

If you opt out of the Melanoma Community Registry you will stop receiving information about future educational events in your community or research opportunities, but information previously provided will not be deleted.

COMMERCIAL DEVELOPMENT

Mole images and information obtained from you in this project 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 information.

COSTS:

There will be no cost to you to participate in this study other than to your mobile data plan if applicable.

LIABILITY:

If you believe you have been injured or harmed as a result of participating in this research and require treatment, contact the Principal Investigator, Sancy Leachman at (503) 494-8533.

If you are injured or harmed by the study procedures, 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.

PARTICIPATION:

If you have any questions, concerns, or complaints regarding this study now or in the future, contact Sancy Leachman at (503) 494-8533 or Tracy Petrie at (503) 494-8410.

This research is being overseen by an Institutional Review Board ("IRB"). You may talk to the IRB at (503) 494-7887 or irb@ohsu.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get more information or provide input about this research.

You may also submit a report to the OHSU Integrity Hotline online at <https://secure.ethicspoint.com/domain/media/en/gui/18915/index.html> or by calling toll-free (877) 733-8313 (anonymous and available 24 hours a day, 7 days a week).

Your participation in this study is voluntary. You do not have to join this or any research study. You do not have to allow the use and disclosure of your health information in the study, but if you do not, you cannot be in the study.

Although you can withdraw from the study at any time from within the app, you cannot withdraw the coded study data that have already been distributed. If you withdraw from the study, we will stop collecting new data but the coded data that you have already provided will not be able to be destroyed or deleted.

The Study Principal Investigator or the study funder may also withdraw you from the study without your consent at any time for any reason, including if it is in your best interest, you do not consent to continue in the study after being told of changes in the research that may affect you, or if the study is cancelled.

We will give you any new information during the course of this research study that might change the way you feel about being in the study.

Your health care provider may be one of the investigators of this research study and, as an investigator, is interested in both your clinical welfare and in the conduct of this study. Before entering this study or at any time during the research, you may ask for a second opinion about your care from another doctor who is in no way involved in this project. You do not have to be in any research study offered by your physician.

The participation of OHSU students or employees in OHSU research is completely voluntary and you are free to choose not to serve as a research subject in this protocol for any reason. If you do elect to participate in this study, you may withdraw from the study at any time without affecting your relationship with OHSU, the investigator, the investigator's department, or your grade in any course.

SIGNATURES:

Your signature below indicates that you have read this entire form and that you agree to be in this study.

We will email you a copy of this signed form.

Name of Adult Participant

Signature of Adult Participant

Date

Email

Sharing Option