OREGON HEALTH & SCIENCE UNIVERSITY

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.

OREGON HEALTH & SCIENCE UNIVERSITY

IRB#: 16038

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
	Dan Webster, PhD	(650) 799-4304
	Ravi Samatham, PhD	N/A

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, 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 repository, the Melanoma Community 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. 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 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 depending on the number of moles you choose to measure.

Your identifiable data may be shared in an ethically controlled way with the Melanoma Community Registry under the IRB 10561 protocol if you consent. As part of the Melanoma Community Registry you may be contacted via the email you provide and given the opportunity to participate in new research opportunities.

With this consent, your identifying information will be removed as described below and 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 will crop images and make a best effort to remove those with identifiable marks before making them available.

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

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 approval from the Principal Investigator on this protocol via a data sharing agreement 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

IRB Approved: 12/29/2016
Approval Expires: 12/28/2017

OREGON HEALTH & SCIENCE UNIVERSITY

IRB#__10561____

Research Repository Consent Form

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

PRINCIPLE INVESTIGATOR:	Sancy Leachman, MD, PhD	503-494-8533
REPOSITORY GUARDIANS:	Lisa Domenico, MBA	503-418-5332
	Tracy Petrie, PhD	503-494-8410
	Eric Smith, MBA	503-494-2316
STUDY COORDINATORS:	Ravi Samatham	na
	Anuja Shah, MPH	503-418-3167
	Elizabeth Stoos	503-418-9356
	Faith Tirrell	503-418-9314

FUNDED BY: OHSU Department of Dermatology and Knight Cancer Institute, Colorado Foundation for Public Health & the Environment, N.L. Tartar Trust

ABOUT RESEARCH REPOSITORIES

Generally, a research repository collects, stores and distributes data for use in future research projects. Storing and gathering numerous data together can help to conduct future research and avoid re-collecting it over and over again. With this stored information and samples, researchers may understand better how the human body works, develop new tests to find diseases, find new ways to treat diseases, or develop new products, such as drugs. When researchers collect and store data together and use them for different kinds of research in the future, or share them with other scientists, this is called a research repository.

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

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.

PURPOSE:

The purpose of this repository is to build a cohort, called Melanoma Community Registry, of melanoma patients, family members and friends. This registry will serve as a data repository for future research and thus will collect, store and/or share data for and with melanoma researchers for an indeterminate period of time. Beyond research, it will be a means to communicate with you information about community outreach and educational events. We plan to enroll approximately 100,000 people in this repository. The data would include:

1. Key information about you collected during consent, such as email address, date of birth, zip code of current residence and personal/family history of melanoma.

2. Responses to a variety of questionnaires about your personal and family health history, eye color, hair and skin characteristics, behaviors that might impact skin cancer risk (sun exposure), circumstances that impact your ability to access care and other social data.
3. Photographs of skin lesions you wish to share via cellphone apps, pictures in your medical records or what you may provide at community events.
4. Links to connect your information in this repository to your data in other ethics-approved data sources such as the BioLibrary, medical records, pathology reports, etc.
5. Information about your interests to volunteer unique skills or tap personal networks to raise awareness/educate in communities and bring the "patient voice" to the research process by providing feedback on survey development, looking at educational materials, sharing your story with media (with permission), and other outreach activities.

PROCEDURES:

If you take part in this repository, you are allowing us to:

- **Contact you, by email, and request you complete on-line surveys or questionnaires or participate in discussion sessions (i.e. focus groups) on a range of topics** such as your history of sun exposure, use of sun protective clothing or sunscreens, personal history of melanoma including stage and depth, relations in your family who have also had melanoma, obstacles faced, feedback on written or oral materials that are intended for the public, etc.
- **Request you complete medical release forms so we can get and store records of your care and diagnostic results**. This will allow us to have this important medical information regardless of where you received care.
- **Maintain linkages that allow us identify your data**, as opposed to being anonymous, so we can study your unique characteristics. This will allow is to, for example, look at survey data that indicates your hair and eye color, amount of lifetime sun exposure, pathology reports, genetic information, and clinical/treatment data to study potentially important relationships.
- **Query the list of names in the registry to aid other researchers** in enrolling in their studies using data already collected. This may or may not include the need to re-contact you. This can potentially speed the progress in other melanoma-related studies.
- **Connect you to other melanoma-related community organizations and activities.** There are many activities that take place outside an academic medical center that may be of interest to you. We will make you aware but will not give your information to any group. This will be informational only and will require you to contact them if interested.

WHAT WILL HAPPEN TO THE DATA?

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. All the data we collect will be stored on secure, encrypted servers behind an OHSU firewall. We will establish a coded identifier of letters and numbers (not name or social security number) that can link your data from multiple sources (clinical records, survey responses). Only the IRB-approved personnel and other OHSU personnel working on this study will be authorized access to these identifiable data. We will store this data indefinitely, unless you expressly chose to withdraw from this study.

Because melanoma is a cancer of the skin, photographs are important data for our research. During this study you may provide or have photos taken. We will use the photographs for research publications and academic educational opportunities. We will conceal your identity by using a black bar over eyes or other identifiable features. We will obtain your permission (media release) to use photos used for public education or study marketing purposes.

By being part of this repository, the data you provide can assist other researchers in their studies. We share data with qualified researchers following specific criteria. All requests for data release are

reviewed by the Principal Investigator and the Guardian of this repository to ensure data are transferred, used, and stored in a secure and confidential manner.

FUTURE STUDIES:
As described above, data we collect or generate may be given to other researchers as part of the search for causes and treatments of diseases. This may include, but is not limited to, studies of scientific or biologic relevance to cells involved in melanoma development. Your authorization to use your health information will never expire unless you revoke it. The samples and clinical information will be labeled and stored as described in the PRIVACY & CONFIDENTIALITY section.

WILL YOU RECEIVE RESULTS FROM RESEARCH INVOLVING YOUR DATA?
You will not receive results from data you provide. In most cases, the studies are being conducted by researchers outside of this data repository and therefore, our study personnel would not have knowledge of their findings. In addition, it is possible that researchers conducting future studies will receive only information that is coded and does not include identifiers (your name) so contacting you is not possible.

RISKS AND DISCOMFORTS:

You may answer questions about your or a family member's experience with cancer. Some of these questions may seem very personal or embarrassing. They may upset you. You may refuse to answer any of the questions that you do not wish to answer. If the questions make you very upset, we will help you to find a counselor.

Although we have made every effort to protect your identity, there is a small risk of loss of confidentiality. If the results of any studies of your genetic makeup were to be accidentally released, it might be possible that the information we will gather about you as part of this research repository could become available to an insurer or an employer, or a relative, or someone else outside the repository. Even though there are discrimination and confidentiality protections in both Oregon law and Federal law, there is still a small chance that you could be harmed if a release occurred.

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. Be aware that this federal law does **not** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination if you have already been diagnosed with the genetic disease being tested.

BENEFITS:
You will not personally benefit from participating in this repository. However, by serving as a participant, you may contribute new information which may benefit patients in the future.

ALTERNATIVES:
You may choose not to participate in this repository.

PRIVACY & CONFIDENTIALITY PROTECTIONS:

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

We will take steps to keep your personal information confidential, but we cannot guarantee total privacy. We will create a coded identification (letters and numbers) instead of names. This coded ID will be accessed only by study personnel authorized to receive identifiable data as described earlier. The investigators, study staff, and others at OHSU may use the information we collect and create about you in order to maintain and oversee this research repository and to conduct future research projects.

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

- The funder of this study and the funder's representatives
- The Food and Drug Administration
- The Office for Human Research Protections, a federal agency that oversees research involving humans

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.

LIABILITY:

If you believe you have been injured or harmed while participating in this repository and require immediate treatment, contact your regular doctor or primary care physician.

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.

COMMERCIAL DEVELOPMENT

Samples and/or information including any photographs about you or obtained from you in this research 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.

PARTICIPANT RIGHTS:

If in the future you decide you no longer want to participate in this research repository, we will destroy all your information provided. However, if your information or genetic samples are already being used in an on-going research project and if their withdrawal jeopardizes the success of the entire project, we may ask to continue to use them until the project is completed.

This research is being overseen by an Institutional Review Board (IRB). You may talk to them 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).

PARTICIPATION:

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

If you do join the repository and later change your mind, you have the right to quit at any time. This includes the right to withdraw your authorization to use and disclose your health information. If you choose not to join this repository, or if you withdraw early from the repository, there will be no penalty or loss of benefits to which you are otherwise entitled, including being able to receive health care services or insurance coverage for services. Talk to the investigator if you want to withdraw from the

repository.

If you no longer want your health information to be used and disclosed as described in this form, you must send a written request or email stating that you are revoking your authorization to:

OHSU Department of Dermatology
3303 SW Bond Ave, Portland, OR 97239
Attn: Melanoma Community Registry Coordinator

Or WarOnMelanoma@ohsu.edu

Your request will be effective as of the date we receive it. However, health information collected before your request is received may continue to be used and disclosed to the extent that we have already acted based on your authorization.

Your health care provider may be one of the investigators of this research repository, and as an investigator is interested in both your clinical welfare and in the conduct of this research. You do not have to be in any research study offered by your physician. Your health care outside the research, the payment for your health care, and your health care benefits will not be affected if you do not sign this form.

If you have any questions, concerns, or complaints regarding this research repository now or in the future, contact Sancy Leachman, MD, PhD at (503) 494-8533 or contact a study coordinator at (844) 300-SPOT (7768).

Language for: ONLINE CONSENT: (not included on printed copy)
Your submission of this electronic form by clicking on "I ACCEPT" button below indicates that you have read this entire form and that you agree to be in this repository. If you change your mind about participation at any time, now or in the future, contact the study team listed on the first page of this consent form.

I, **ACCEPT**.

OR

I am under age 18, AND a PARENT, GUARDIAN OR LEGALLY AUTHORIZED REPRESENTATIVE to **ACCEPT** ON HIS/HER BEHALF.