

## STUDY INFORMATION AND CONSENT to RESEARCH

**TITLE:** Mole Mapper Study

**PROTOCOL NO.:** 201510920  
WIRB® Protocol #20151976

**SPONSOR:** Sage Bionetworks

**INVESTIGATOR:** Stephen H. Friend, MD, PhD  
1100 Fairview Ave. North  
Seattle, Washington 98109-4433  
United States

**STUDY-RELATED  
PHONE NUMBER(S):** Andrew Trister  
1-206-667-2115 or toll-free at: 1-844-693-2137

### SUMMARY

You are invited to participate in a research study to understand skin health and melanoma risks. The purpose of this form is to help you decide if you want to participate in this study. Please read the information carefully.

You should not join the research study until all of your questions are answered.

Participating in a research study is not the same as receiving medical care. The decision to join or not join the research study will not affect your medical benefits.

### PURPOSE OF THE STUDY

Moles change in size, color, and number during our lifetimes. Rarely, some moles become cancerous (melanoma). This study will collect individual's information on melanoma risks together with mole measurements and photos using an iPhone application and the iPhone camera. The goals of this study are 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 the disease.

### PROCEDURES

#### What will you be asked to do?

If you decide to join the study you will need to download the free study application on your iPhone and register to the study. Then, we will ask you to answer few questions about

yourself and take photographs of your moles using the study application your mobile phone camera.

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.

### **How long will I be in the research study?**

This study will last about twelve months. However the application (“app”) 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.

### **How many people will take part in this study?**

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

## **RISKS, DISCOMFORTS, AND INCONVENIENCES**

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.

## **POTENTIAL 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.

## **VOLUNTARY PARTICIPATION AND WITHDRAWAL**

- You should not feel obligated to participate in this study.
- Your questions should be answered clearly and to your satisfaction.
- You have a right to download or transfer a copy of all of your study data.
- By agreeing to participate you do not waive any of your legal rights.
- You may withdraw from this study at any time by contacting the Study Principal Investigator, Dr. Stephen Friend, by email [molemapperstudy@sagebase.org](mailto:molemapperstudy@sagebase.org) or at 1-206-667-2115
- Your decision not to participate, or to withdraw, will not result in any penalty or loss of benefit to which you would be otherwise entitled.

Although you can withdraw from the study at any time, 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 sponsor 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.

## **PAYMENT**

You will not be paid and will receive no financial benefit for being in this study.

## **COSTS**

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

## **COMPENSATION FOR INJURY**

**THIS STUDY DOES NOT PROVIDE ANY COMPENSATION, HEALTH OR MEDICAL CARE TO PARTICIPANTS.**

If you are injured as a direct result of your participation in this study, the Principal Investigator or the medical monitor and the research study staff will assist you in obtaining appropriate medical treatment. Your medical insurance, managed care plan, or other benefits program will be billed for this treatment. You will be responsible for any associated co-payments or deductibles as required by your insurance.

If costs of care related to such an injury are not covered by your medical insurance, managed care plan or other benefits program, you may be responsible for these costs. The

sponsor will not routinely pay charges that your insurance does not cover. No payment is routinely available from the study sponsor.

## **ALTERNATIVES**

Since no medical treatments are provided during this study there are no alternative therapies. The only alternative is to not participate.

## **AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES**

### **What personal information will be collected, used, or disclosed?**

Your personal information that may be collected, used, or disclosed in connection with this research study may include, but is not limited to your account information, answers to study questions and the photographs you take of your moles.

### **Who may use and disclose your Personal Information?**

The study sponsor, investigators, study coordinators and study staff may use and disclose your personal information to do the research described above or as required by law to:

- The US Department of Health and Human Services and the Office for Human Research Protection and other agencies for verification of the research procedures and data,
- Western Institutional Review Board® (WIRB®) or other Institutional Review Board who watch over the safety, effectiveness and conduct of the research,
- Others, if the law requires.

In addition your name and contact information will be sent to the IRB-approved War on Melanoma Community Registry database managed by researchers at Oregon Health Science University [<http://www.ohsu.edu/xd/health/services/dermatology/melanoma-community-registry/>]. Information in the registry will be stored on a secure Redcap server at OHSU. Taking part in this registry enables the OHSU War on Melanoma researchers to inform you about other specific melanoma-related educational and research opportunities you may be eligible to participate in. You can choose to participate or not and can opt out of the Melanoma Community Registry at any time.

### **When will my authorization expire?**

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.

## **PRIVACY, CONFIDENTIALITY and DATA PROTECTION**

We are committed to protect your information and keep your identity as confidential as possible, however total confidentiality cannot be guaranteed.

### **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](http://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 iPhone 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 our data practices in the context of the Synapse research platform, see the [Synapse Governance Overview](https://www.synapse.org/#!/Wiki:syn2502577/ENTITY) [<https://www.synapse.org/#!/Wiki:syn2502577/ENTITY>]

### **How is my coded study data used in research?**

Your study data (without your name) will be added to the data of other study participants and analyzed by the study team. The research team will analyze the combined data and report findings back to the community through scientific publications.

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](http://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.

**Is there risk to privacy?**

We take great care to protect your personal information, but there is a slight risk of loss of 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. 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.

**SOURCE OF FUNDING FOR THE STUDY**

The sponsor is Sage Bionetworks, <http://sagebase.org/>, with some funding from the Robert Wood Johnson Foundation.

**QUESTIONS**

Contact Drs Stephen Friend or Andrew Trister by email at [[molemapperstudy@sagebase.org](mailto:molemapperstudy@sagebase.org)] or call 1-206-667-2115 (toll-free at +1-844-693-2137) for any of the following reasons:

- If you have any questions about this study or your part in it, or
- If you have questions, concerns or complaints about the research, its procedures, risks and benefits, or alternative course of treatment
- if you feel that being a part of this study has hurt you.

*Independent Contact:* If you are not satisfied with how this study is being conducted, or if you have any questions, concerns, input or complaints about the research or about your rights as a participant, please contact:

Western Institutional Review Board® (WIRB®)  
1019 39th Avenue SE Suite 120  
Puyallup, WA 98374-2115  
Telephone: 1-800-562-4789 or 360-252-2500  
E-mail: [Help@wirb.com](mailto:Help@wirb.com).

WIRB is a group of people who independently review research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

*War on Melanoma Community Registry:* If you have questions or want to opt out of the Melanoma Community registry, contact the registry personnel at 1-844-300-SPOT (7768) or [WarOnMelanoma@ohsu.edu](mailto:WarOnMelanoma@ohsu.edu).

*For technical support with the app you can email [molemapper@gmail.com](mailto:molemapper@gmail.com)*

## CONSENT

I have read about this research study (or it has been read to me). All my questions about the study and my part in it have been answered. It has been explained to me that my participation in this study is voluntary and I freely consent to be in this research study.

I expressly authorize the collection, processing, use and disclosure of my study data, including health information in electronic database(s) for use in research as indicated in the privacy, confidentiality and data protection section, the data sharing setting through the app preferences, and the study Privacy Policy

I expressly authorize the transfer of my personal data, including health information, to Sage Bionetworks in the United States for research and data analysis. I understand that data protection laws in the United States may differ from the laws in the country where I reside.

By signing this consent form I have not given up any of my legal rights. I am free to withdraw my consent at any time and free of charge without giving reason.

YOUR SIGNATURE INDICATES THAT YOU HAVE READ AND UNDERSTAND THE ABOVE INFORMATION AND THAT YOU HAVE DECIDED TO PARTICIPATE BASED ON THE INFORMATION PROVIDED. A COPY OF THIS FORM WILL BE EMAILED TO YOU.

Data sharing preferences:    Share broadly       or       Share sparsely

Name of adult participant: \_\_\_\_\_

Email: \_\_\_\_\_

Signature and Date: \_\_\_\_\_