Permission to Take Part in a Human Research Study

Title of Research Study: Targeted melanoma detection with skin self-examination

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Investigator: June K. Robinson, MD

Supported By: This research is supported by the National Institutes of Health.

Key Information:
The first few pages of this document include a summary of this study to help you decide whether or not to participate. Detailed information is provided after the summary.

Why am I being asked to take part in this research study?
We are asking you to take part in this research study because you are a woman 18 years of age or older that recently had a screening mammogram at Northwestern Medicine and have identified yourself as "at-risk" for getting melanoma. In addition, you have internet access and are willing to perform skin-self-examinations, invite a skin check partner to help check your skin, complete monthly surveys for 3 months, and receive monthly text messages to your personal phone from the research study team.

What should I know about a research study?
- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?
The purpose of this research study is to determine the helpfulness of a skin self-examination program for women who identify as "at-risk" for getting melanoma, a deadly type of skin cancer.

Potential benefits of participating in this study are the ability and/or enhanced ability to detect a melanoma in the earlier, curable stages. A potential harm is anxiety related to detection of a concerning mole.

How long will the research last and what will I need to do?
We expect that you will be in this research study for a total of 3 months after your baseline online survey.

You will be asked to complete 3 monthly surveys (one survey a month) after your baseline online survey. In addition, you will receive monthly text messages to your personal mobile phone. After completing the 3rd monthly survey, the study team will check your survey responses and access your medical record to collect data related to any doctor visits related to medical care for a concerning mole. This research does not include any skin exam by a doctor, biopsy of a concerning mole, or treatment of melanoma.

More detailed information about the study procedures can be found under the section: **What happens if I say, "Yes, I want to be in this research".**

Is there any way being in this study could be bad for me?

Participating in this study may cause emotional distress resulting from the discovery of a concerning mole that may prove to be a melanoma or non-melanoma skin cancer. If a concerning mole is identified there is the option to seek an appointment with a doctor for standard medical care, check the concerning mole again in the following months for change, or choose to do a test of your skin cells from the concerning mole using a home test kit where you remove the outer layers of skin cells with an adhesive patch and mail the "self-sample" to a special lab that looks for genes related to melanoma.

More detailed information about the risks of this study can be found under **"Is there any way being in this study could be bad for me? (Detailed Risks)"**

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include an enhanced ability to detect a melanoma in the early, curable, phases.

What happens if I do not want to be in this research?

Participation in research is voluntary. You decide whether to participate. If you choose to not participate, there will be no penalty to you or loss of benefit to which you are entitled.

Your alternative to participating in this research study is to not participate.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

Whom can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at 312- 503- 5918.

This research has been reviewed and approved by an Institutional Review Board (IRB). You may talk to them at (312) 503-9338 or irb@northwestern.edu if:

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

How many people will be studied?

We expect about 1000 women will be participating in this research study. Five hundred women, who have obtained a screening mammogram at the Northwestern Medicine Lynn Sage Breast Center, and 500 women who have obtained a screening mammogram at other Northwestern Medicine Breast Centers will be in the study.

What happens if I say "Yes, I want to be in this research"?

At this time, if you say "yes, I want to be in this research" at the end of this Consent Form, you will be randomized into one of two study groups, Group 1 or Group 2. Group selection will be automated using a specific formula generated by Northwestern University's Department of Preventative Medicine statistical team to randomly place you in one of the two groups. Randomization is like the toss of a coin, such that you have a 50/50 chance of being assigned to Group 1 or Group 2. You and the study doctor will not be able to choose which group you participate in.

You will complete a baseline survey, regardless of which study Group you are in. This survey will collect basic information such as your legal name, address, educational background, skin cancer knowledge, healthy lifestyle knowledge, skin type knowledge, demographic information. This survey will take about 15 minutes to complete. In addition, regardless of which Group you are assigned to, your medical record will be accessed and the following information will be extracted from your medical record for research purposes: the doctor's diagnosis of a concerning mole(s), if a skin biopsy of the mole is performed then the results of the biopsy will be obtained from your medical record. Your medical record may be accessed until June 30, 2021.

After you have provided this informed Consent, you will be randomized into Group 1 or 2.

Group 1
If you are randomized into Group 1 your participation in this study will last 3 months. You will be instructed to download a healthy lifestyle brochure and a single page reminder. After you read the brochure, you may place the reminder in your home in an easy to see location to help remind you of the healthy living activity your wish to do. Each month you will receive a healthy lifestyle text message to your personal phone that has tidbits of information to enhance your education about healthy living. In addition, you will also receive a monthly survey that asks about healthy living and mole checks. When you have completed 3 months of participating in the study, you may request a PDF file of the skin self-examination brochure describing how to check your moles. This brochure will provide information on how you may be able to identify a concerning mole that may or may not be a melanoma, information on how to select and work with a skin check partner, and how to score a concerning mole to help determine if you should see a doctor about a concerning mole. At the end of the 3-month study, your medical record will be checked for 2 more months to find out if you had a visit with a doctor about a concerning mole, if the mole was biopsied and the results of the biopsy. At the end of the study, your will be asked to make a choice about receiving compensation as an Amazon electronic gift card.

Group 2
If you are randomized into Group 2 your participation in this study will last 3 months. You will be instructed to download a skin self-examination brochure and a single page reminder. You may choose to place the reminder in a place in your home that you can easily see to help remind you to do monthly skin self-examination. You will read the brochure with your skin check partner and you may refer to the brochure as you do the monthly skin self-examinations. Each month, you will be reminded to complete your skin self-examination, set monthly goals, and engage a skin check partner to help check your skin in the hard to see areas (like your back), and to assist you with the monitoring of any concerning moles, as well as new moles, for a total of 3 months after your baseline visit. On the downloaded brochure and monthly survey, you will also track specific details and score any concerning moles. At the end of the 3 month study, your medical record will be checked for 2 more months to find out if you had a visit with a doctor about a concerning

mole, if the mole was biopsied and the results of the biopsy. At the end of the study, your will be asked to make a choice about receiving compensation as an Amazon electronic gift card.

Regardless of which Group you are assigned to:
If the score of the concerning mole increases, and you indicate this on the monthly survey, at any time during the 3 months, you will have three options for how to proceed with the concerning mole.

1. One option will be that you continue to monitor the concerning mole or moles for evidence of change for the 3 months of the study. If a concerning mole changes with an increase in the score of the mole, then you will be offered a choice of performing mole self-sampling at home (see item 3) or you may choose to make an appointment with a doctor about the mole.
2. You may decide not to monitor a concerning mole for change and may choose to seek an appointment with a doctor about the concerning mole (s).
3. Another option during the 3-month study will be to perform mole self-sampling at home using a kit that will be mailed to you. For self-sampling, you will collect a sample of cells for analysis of genes related to melanoma from the concerning mole using four small adhesive patches that will be provided to you in a kit that is mailed to you. The directions for collecting the cells in the kit tell you to gently cleanse the skin over the surface of the mole with an alcohol pad. Before each of the 4 adhesive patches are applied, take a gauze pad and rub the surface of the mole. Then, you place the adhesive patch onto the surface of the mole and firmly make 5 circular motions over the entire adhesive patch. Next you gently remove the adhesive patch and place it onto cardboard tray. Place the tray into the collector bag and return the sample using the FedExp mailing envelop.

   If the mole self-sampling kit is selected as an option, the kit, directions, and postage for the kit to be sent to the testing lab, DermTech, will be provided to you by Federal Express mail to the address that you provide. Upon completing the mole self-sampling and mailing the specimen to DermTech, it will take 3-5 days for the results to be provided to Dr. Robinson. You will not obtain the report of your laboratory results from DermTech, but instead you will receive a phone call (or an email if you prefer) from Dr. Robinson with the results of the gene testing of your cells. If the results show that the mole may be a melanoma, then the doctor will recommend that you have a skin biopsy of the mole. This kit is currently available for use by any doctor and may be available to you without participation in this research. This research study makes the gene test available to you with no cost to you.

If you used the mole self-sampling kit option, you may be asked as an option, to participate in a telephone end of study interview with Dr Robinson or with a member of the study team to obtain your feedback on your experience with performing mole self-sampling. The study team member will also ask you general questions about the research study, study materials, and overall anxiety related to detection of concerning moles. You are not required to participate in the end of study interview. The study team will also ask, at the end of this consent form, if you will or will not allow audio recording of the end of study interview for data analysis purposes. You may not allow the audio recording, and still participate in the end of study interview.

If you choose to see a doctor about a concerning mole, the study team will assist you in locating a doctor if you do not have one. If you request, the study team is available to work with a doctor to promptly get you an appointment for a possible skin biopsy.

If throughout the 3 months of doing skin self-examinations with a skin check partner, you tell the study team that you have found a concerning mole on your partner that was identified during a

partner skin check, an opportunity for one mole of your partner to be self-sampled in the same way that you are self-sampling will be available to your partner at no cost if your partner contacts the study team to express such interest and then provides Consent to participate. Once the partner contacts the study team for self-sampling his/her mole, an eligibility questionnaire, followed by a Consent Form will be sent to your skin check partner. After the Consent is completed, the kit will be sent to your partner. The process of sharing gene results with your skin check partner is the same as your process, however, for your partner, we will not be accessing their medical record.

Regardless of which group you are in; you will have the opportunity to download the skin self-examination brochure to read.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible for completing 3 monthly online surveys or telephone visits to complete the survey after your baseline online survey. You will take part in the research for a total of 3 months—with 3 monthly surveys/telephone visits after the baseline visit.

What happens if I say "Yes", but I change my mind later?

You can leave the research at any time; it will not be held against you.

If you decide to leave the research, contact the investigator, Dr. June Robinson, so that the investigator can learn if you wish not to be contacted further about this research or if you wish the study team not to continue to access your medical record. Any information that is already collected for research purposes, including what you provided, will be retained in association with your study number in the study records.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment.

Detailed Risks: Is there any way being in this study could be bad for me?

The potential risks related to your participation in this study include anxiety related to finding a concerning mole. If you report excessive anxiety, a referral for psychological support will be provided to you. In addition, since this study is not designed to detect all concerning moles, new skin cancers may arise during the study that are not detected. Your participation in this study does not replace the need for your ongoing health care by your primary care doctor.

This study involves the use of your identifiable, personal information and there is a chance that a loss of confidentiality could occur. The researchers have procedures in place to lessen the possibility of this happening. See the section below titled: **"What happens to the information collected for the research?"**

Will it cost me anything to participate in this research study?

Taking part in this research study will not lead to any costs to you.
If you decide to see a doctor as usual standard care to assess a new and/or concerning mole, the cost of the standard medical care will not be covered by the study. In addition, the biopsy and treatment of any concerning mole will not be covered by the study.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include the potential for you to improve your ability to detect concerning moles.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health (NIH). The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings; for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you. You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

All study-related information will be included as data (surveys, interview notes, audio recordings, and your medical record data). All research data will be coded at all times and linked only with a study ID # to your coded identifying information.. Our study data are guarded against outside entry by Northwestern's own firewall of encryption that provides protection against hackers.

The IRB, the Northwestern University Office for Research Integrity, the US Office of Research Integrity (ORI), the US Office for the Protection of Human Research Protections (OHRP), and the National Institutes of Health (NIH) may be granted direct access to your medical records to conduct and oversee the research. This Consent form authorizes this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

A description of this clinical trial, NCT, will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Data Sharing

De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

What else do I need to know?

If you agree to take part in this research study, we will pay you a $20 Amazon electronic gift card for completing the baseline survey and a $15 Amazon electronic gift card for each completed monthly survey for 3 months ($65 will be paid after completing the final survey). If you complete the telephone exit interview about your experience using the mole self-sampling

kit, you will receive an additional $20 in the form of an Amazon electronic gift card. The total amount you can receive for this study is $65 ($85 if you are selected and complete a telephone exit interview) in the form of an Amazon electronic gift card. The Amazon gift may not be used to pay a premium to Amazon for free shipping. We will not pay additional shipping costs, and if there is an expiration date for use of the card, or any activation fee, or any other fees of any sort, then these will not be paid.

HIPAA Authorization

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Your health information we may collect and use for this research includes:

- Information about moles or melanoma from Dermatology visits or visits with other doctors
- Biopsy pathology reports for concerning skin lesions/moles
- Treatment if a melanoma is found

This consent expires on June 30, 2021. After this date, Northwestern University may not gather new information about you, use or disclose your personal health information collected in this study for any purpose other than the research study described in this consent unless Northwestern University obtains permission to do so from you

During this study, you may be coming to a Northwestern Memorial Healthcare Corporation entity (for example, Northwestern Memorial Hospital, Prentice Women's Hospital) to get clinical services, such as lab tests, needed for the study. When that happens, you will be scheduled for these services through the NMHC computer system. When a clinical exam or lab is done by NMHC or one of its employees for the purpose of this research study, that information will be kept in both NMHC's clinical records and in the study records.

The following clinical providers may give the researchers information about you: all current and previous health care providers, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH).

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of Northwestern University and its clinical partners (or affiliates): the Northwestern University Institutional Review Board Office and Office for Research Integrity; the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or University policy [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator's office].

The following entities may receive your health information:

- Authorized members of the Northwestern University workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board.
- Clinical affiliates, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), Northwestern Lake Forest Hospital (NLFH), and the Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's). Your participation in this clinical trial may be tracked in an electronic database and may be seen by investigators running other trials that you are enrolled in and by your healthcare providers.
- Clinical affiliates, including but not limited to Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH), for purposes including, but not limited to, the affiliate's provision of care to you and/or the affiliate's scheduling of appointments and/or billing activities.
- Other University research centers and University contractors who are also working on the study,
- Study monitors and auditors who make sure that the study is being done properly,
- The National Institutes of Health, who is sponsoring the study, and that company's contractors and partners.
- Government agencies and public health authorities, such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).
- Registries or other research-related databases

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission.

Also, Federal law/42 CFR Part 2 prohibits unauthorized disclosure of these records.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Unless you revoke your consent, it will expire on June 30 , 2021.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

PI's Name: June K. Robinson, MD
Institution: Northwestern University
Department: Department of Dermatology
Address: 645 N Michigan Ave, Suite 1053
Chicago, IL 60611

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

A copy of this signed consent document, information about this study, and the results of any test or procedure done may be included in your medical records and may be seen by your insurance company.

Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing an X next to each activity or select an X in the corner of your browser.

I agree	
_____	The researcher may audio record me to aid with data analysis. The researcher will not share these recordings with anyone outside of the immediate study team. The recording of your voice will be destroyed as soon as data analysis is completed.]
_____	The researcher may contact me in the future to see whether I am interested in participating in other research studies by the Principal Investigator of this study.

Consent

To obtain a copy of this consent for your records, you can print it from the screen.

Signature Block for Capable Adult:

Your signature documents your permission to take part in this research.

_____ _____
Signature of Participant Date

_____
Printed Name of Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent