RUTGERS
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RUTGERS HEALTH

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CONSENT TO TAKE PART IN A RESEARCH STUDY

Title of Study: A digital intervention to improve skin self-examination among melanoma survivors

Principal Investigators: Sharon Manne, PhD and Carolyn Heckman, PhD

STUDY SUMMARY: This consent form is part of an informed consent process for a research study. It will provide information that will help you decide whether you want to take part in this study. It is your choice to take part or not.

The **purpose of the research** is to learn whether an online program focusing on improving skin self-examinations and sun safety is helpful for melanoma survivors.

If you take part in this study, you will be asked to:

- Carefully view and complete the online program focusing on improving skin self-examinations and sun safety
- Complete 5 online surveys over the course of 18 months
- Provide feedback on the online program you viewed

After you complete the 1st survey, you will be randomly assigned to view one of the online programs developed by the study team. You will be asked to complete surveys at

- 3 months
- 6 months
- 12 months
- 18 months after you complete the 1st survey.

Your time in the study will take about 18-19 months. Each survey will take you about 15-30 minutes to complete. Viewing the online program should take approximately 1 hour. You may be asked to return to it again during the course of the study.

We will be selecting a subset of 30 people to participate in interviews to give feedback on the online program. If you are selected to take part in the interviews, we will contact you after you have viewed the online program. These interviews should take approximately 60 minutes to complete.

Possible harms or burdens of taking part in the study may be feeling upset thinking about skin cancer . Possible benefits of taking part may be learning information about skin self-exams.

The information in this consent form will provide information about the research study and what you will be asked to do if you choose to take part. If you have any questions now or during the study, if you choose to take part, you should feel free to ask them. You should expect to be given answers you completely understand.

After your questions have been answered and you wish to take part in the research study, you will be asked to agree to this consent form.

You are not giving up any of your legal rights by agreeing to take part in this research or by agreeing to this consent form.

Who is conducting this study?
Dr. Sharon Manne and Dr. Carolyn Heckman are the Principal Investigators of this research study. A Principal Investigator has the overall responsibility for the conduct of the research.

There are often other people who are part of the research team.

Dr. Sharon Manne may be reached at 732-235-6759.

Dr. Carolyn Heckman may be reached at 732-235-8830.

A member of the study team will be asked to review this informed consent.

You will be given a copy of the form to keep.

Sponsor of the Study: National Institutes of Health (NIH)/ National Cancer Institute (NCI)

Why is this study being done?
The purpose of this study is to learn whether an online program that focuses on improving skin self-examinations and sun safety is helpful for melanoma survivors.

Who may take part in this study and who may not?

Participants must:

- Have been diagnosed with stage 0–III cutaneous malignant melanoma and be 3 months to 5 years post-surgery.
- Have no current evidence of melanoma
- Meet study criteria for frequency of conducting skin self-exams
- Be at least 18 years old
- Have internet access and
- Be able to speak/read English

Why have I been asked to take part in this study?
You are being asked to take part in this study because you are a Melanoma cancer survivor who meets the criteria described above.

How long will the study take and how many subjects will take part?

Participants will include up to 300 Melanoma cancer survivors. Your time in the study will take about 18-19 months. Each survey will take you about 15-30 minutes to complete.

Viewing the online program should take about 1 hour. You may be asked to return to it again during the study. We will be selecting a group of 30 people to participate in interviews. During the interview, you will be asked to give feedback on the online program. These interviews should take about 60 minutes to complete.

What will I be asked to do if I take part in this study?

If you take part in this study, you will be asked to:

- Complete 5 online surveys over a period of 18 months
- View and give feedback on an online program developed by the study team
- You may be 1 of 30 people asked to participate in an interview to give feedback on the online program.

After you complete the 1st survey, you will be randomly assigned, or assigned by 50/50 chance, to view one of the online programs developed by the study team. You will be asked to give feedback on:

- The program including the things you liked or did not like about the online program you viewed.
- The content of the online program
- Its features
- How it looks
- What it was like for you to navigate through the online program.

Study staff may send email or text message reminders or call you to encourage you to login to the online program you have been asked to view. You will be asked to complete surveys at 3 months, 6 months, 12 months, and 18 months after you completed the 1st survey.

The study team will send you an email or text with a link to each survey. All the surveys should take around 15-30 minutes to complete.

You will also be asked to sign a medical release form. The form will allow us to contact your dermatologist or doctor to request information regarding any skin exams you received. We will also collect information about the outcome of the exams.

If you are selected and agree to do the interview, the session will take place via teleconference. The interview will be recorded. A combination of sound, pictures, or video will be made to record your comments during the interview session. The recordings will be used by the study team to take notes on your feedback and record ideas you share about the program(s). You can ask a team member to record sound only if you prefer.

What are the risks of harm or discomforts I might experience if I take part in this study?
It is not expected that you will experience any risks or discomforts from taking part in this study. However, potential risks are
1) breach of confidentiality and
2) emotional distress that might come with being asked questions or reading information about melanoma skin cancer.

If you feel uncomfortable with a question, you can ask to skip the question or withdraw from the study.

If you feel any distress during participation, please let the study team know. A team member who is trained in psychology and works with cancer patients can give you information about professional help.

As with all research that collects protected health information, there is a risk of breach of confidentiality. This risk is rare.

Are There Any Benefits To Me If I Choose To Take Part In This Study?
The benefits of taking part in this study may be learning more information about melanoma skin cancer by reviewing the online program. It is possible that you may not receive any benefit from taking part in this study.

What Are My Alternatives If I Do Not Want To Take Part In This Study?
Your alternative is not to take part in this study.

How Will I Know If New Information Is Learned That May Affect Whether I Am Willing To Stay In The Study?
During the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. You will be contacted if new information is learned that may affect you after the study or your follow-up is completed.

Will There Be Any Cost To Me To Take Part In This Study?
There will be no cost to you to take part in this study.

Will I Be Paid To Take Part In This Study?
You will receive e-gift card payments for completing each of the 5 surveys as follows.

- $15 for Survey 1
- $25 for Survey 2
- $25 for Survey 3
- $25 for Survey 4
- $30 for Survey 5 ($120 maximum if you complete all surveys).

If you are selected to participate in the interview, you will receive a $50 e-gift card for participating.

How Will Information About Me Be Kept Private Or Confidential?
All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed.

You will be assigned a unique study ID number. All records that contain your name, telephone number, email address or other information that could identify you are kept separate from your other information.

Rutgers Cancer Institute of New Jersey uses username/password security measures to restrict access to only those study team members who have permission. Data collected through the Internet will be stored on password protected servers.

We believe that these procedures will be effective in protecting against and minimizing potential risks.

The research team may use or share your information collected or created for this study with the following people and institutions:

- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
- This study's data safety monitoring board
- Non-Rutgers investigators on the study team: (The New Jersey State Cancer Registry and its staff, The Cancer Registry of Greater California (CRGC) and its staff, University of Colorado and its staff, RTI and its staff)
- REDCap program management software, Qualtrics survey software, and members of the Rutgers Cancer Prevention and Outcomes Data Support
- Digital technology development company Radiant Corps

This research is covered by a Certificate of Confidentiality (COC) from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay.

They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state, or local laws require, such as laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others.

The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research.

The COC does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

A description of this clinical trial will be available on ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What Will Happen To My Information—data, recordings and/or images Collected For This Research After The Study Is Over?

After information that could identify you has been removed, de-identified information collected for this research may be used for other research we conduct without obtaining additional informed consent from you.

What Will Happen If I Do Not Wish To Take Part In The Study Or If I Later Decide Not To Stay In The Study?

It is your choice whether to take part in the research. You may choose to take part, not to take part, or you may change your mind and withdraw from the study at any time. If you do not want to enter the study or decide to stop taking part, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for future use of data already collected about you, but you must do this in writing to: Sharon Manne, PhD or Carolyn Heckman, PhD

Rutgers Cancer Institute of New Jersey
120 Albany Street
New Brunswick, NJ 08901

Who Can I Contact If I Have Questions?

If you have questions about taking part in this study, you can contact one of the Principal Investigators:

Dr. Sharon Manne, section of Behavioral Sciences at 732-235-6759.

You can contact Dr. Carolyn Heckman, section of Behavioral Sciences at 732-235-8830.

If you have questions, concerns, problems, information or input about the research or would like to know your rights as a research subject, you can contact the Rutgers IRB or the Rutgers Human Subjects Protection Program via phone at (973) 972-3608 or (732) 235-2866 or (732) 235-9806 OR via email irboffice@research.rutgers.edu, or you can write us at 335 George Street, Liberty Plaza Suite 3200, New Brunswick, NJ 08901.

Consent for Video/Audio Taping

If you are selected for an interview, we are asking for your permission to allow us to audiotape (sound) and videotape (video) as part of the research study.

The recording(s) of your feedback session will be transcribed and used for analysis by the research team. The recording(s) will include your study assigned ID # but not your name. Electronic copies of the recording(s) will be stored on secure servers at Rutgers Cancer Institute of New Jersey.

Any hard copy back-ups of recordings will be stored in a locked file cabinet and labeled with your study assigned subject ID # in the Behavioral Sciences department at Rutgers Cancer Institute of New Jersey. Any transmission of the recordings of the interviews between team members at other participating institutions will be sent via an encrypted email or encrypted hard drive.

The investigator will not use the recording(s) for any other reason than those stated in the consent form without your permission.

You will now be asked if you want to consent to participate in this study.

If you do not wish to take part in the research study, close this window.

If you wish take part in the research, follow the directions below:

Please acknowledge that you have read through this consent form and agree to participate in this study by clicking yes below, which will take you to the first survey.

If you do not wish to participate, click no and this form will close.

Yes No