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RUTGERS HEALTH

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SUBJECT CONSENT TO TAKE PART IN A RESEARCH STUDY

TITLE OF STUDY: Internet Intervention for Sun Protection and Skin Self-Check Behaviors (Phase 2)

Principal Investigator: Elliot J. Coups, PhD

This consent form is part of an informed consent process for a research study and it will provide information that will help you to decide whether you wish to volunteer for this research study. It will help you to understand what the study is about and what will happen in the course of the study.

If you have questions at any time during the research study, you should feel free to ask them and should expect to be given answers that you completely understand.

After all of your questions have been answered, if you still wish to take part in the study, you will be asked to sign this informed consent form.

You are not giving up any of your legal rights by volunteering for this research study or by signing this consent form.

Who is conducting this research study?
Dr. Coups is the principal investigator of this research study. A principal investigator has the overall responsibility for the conduct of the study. However, there are other individuals who are part of the research team. Dr. Coups is conducting the study in collaboration with researchers at the University of Virginia.

Dr. Coups may be reached at: Rutgers Cancer Institute of New Jersey, 195 Little Albany Street, New Brunswick, NJ 08903. Telephone: (732) 235-8076.

The principal investigator or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

Sponsor of the study:
The National Cancer Institute is the sponsor of this research study.

Why is this study being done?
The goal of this study is to test an Internet program to help individuals diagnosed with melanoma to perform skin self-checks and engage in sun protection behaviors.

Why have you been asked to take part in this study?
You have been asked to take part in the study because you were diagnosed with melanoma.

Who may take part in this study?
You may be included in this study if: (1) you were diagnosed with stage 0–III melanoma; (2) you had surgery for your melanoma between 3 and 24 months ago; (3) you do not regularly perform thorough skin self-checks; (4) you do not sufficiently adhere to sun protection recommendations; (5) you are at least 18 years old; (6) you have access to a computer connected to the Internet; and (7) you are able to speak and read English.

How long will the study take and how many subjects will participate?
You will participate in the study for 1 year. Up to 420 people will take part in the study.

What will you be asked to do if you take part in this research study?
You will complete an online survey on four occasions: at the start of the study and then 2, 6, and 12 months later. The surveys will take from 20 to 40 minutes to complete. The surveys include questions about your demographic information, beliefs about melanoma, and your beliefs and experiences conducting skin self-checks and engaging in sun protection behaviors.

After you complete the first survey, you will be randomized to one of two groups. The first group will be given immediate access to an Internet program to help individuals diagnosed with melanoma to perform skin self-checks and engage in sun protection behaviors. The second group will be given access to the Internet program after waiting for 12 months. Randomization means you will be assigned to a group based on chance, like a flip of a coin. Neither you nor the researcher chooses your assigned group. You will have an equal chance of being in either group.

What are the risks and/or discomforts you might experience if you take part in this study?
There are no anticipated physical risks or side effects to you for taking part in this study. There is a small chance that you may experience discomfort or distress associated with answering questions about melanoma, including the potential for disease recurrence. There is also a chance that you may experience upset or distress if you identify a suspicious mole or growth on your skin. If at any time you have concerns about any moles or growths on your skin that could be skin cancer, you should visit your doctor.

Are there any benefits for you if you choose to take part in this research study?
The benefits of taking part in this study may be:

- learning how to perform regular skin self-checks; and
- learning how to engage in sun protection behaviors.

However, it is possible that you might receive no direct personal benefit from taking part in this study.

What are your alternatives if you don't want to take part in this study?
Your alternative is not to take part in the study.

Will there be any cost to you to take part in this study?
No.

Will you be paid to take part in this study?
You will receive a $25 gift card for each online survey that you complete.

How will information about you 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. Your research record will be assigned a code number and your actual name will not be used. Only the study researchers will be able to link the code number to your name. Your research record will be stored in a secure location at Rutgers Cancer Institute of New Jersey. Transfer of electronic data between the research teams at Rutgers University and the University of Virginia will be performed using secure, encrypted methods.

What will happen if you do not wish to take part in the study or if you later decide not to stay in the study?
Participation in this study is voluntary. You may choose not to participate or you may change your mind at any time.

If you do not want to enter the study or decide to stop participating, 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 the use of data already collected about you, but you must do this in writing to Dr. Coups (address shown on page 1).

Who can you call if you have any questions?
If you have any questions about taking part in this study, you can call the study principal investigator, Elliot J. Coups, PhD, Rutgers Cancer Institute of New Jersey at (732) 235-8076. If you have any questions about your rights as a research subject, you can call the Institutional Review Board (IRB) Director at (732) 235-9806.

What are your rights if you decide to take part in this research study?
You have the right to ask questions about any part of the study at any time. You should not sign this form unless you have had a chance to ask questions and have been given answers to all of your questions.

PERMISSION (Authorization) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY

Information about you and your health is personal and private, so this information generally cannot be used in research without your written permission. The next few paragraphs tell you about how researchers want to use and share your health information in this research study. Your information will only be used as described here or as allowed or required by law. Ask questions if you do not understand any part of the research or the use of your health information. If you sign this consent form, you agree to let the researchers use your information in the research and share it with others as described below.

What is the purpose of the research and how will my information be used?
You are being invited to take part in this research study which is described at the beginning of this form. The purpose of collecting and using your health information for this study is to help researchers answer the questions that are being asked in the research.

What information about me will be used?
- Information about your melanoma diagnosis and treatment history.
- Information about your visits to health care providers during the study time period.

Who may use, share or receive my information?
The research team may use or share your information collected or created for this study with the following people and institutions:
- Rutgers University researchers involved in the study
- Non-Rutgers researchers on the study team at the University of Virginia
- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- Study sponsor, the National Cancer Institute
- DatStat, a company whose software is being used in this study

Those persons or organizations that receive your information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by the laws governing them.

Will I be able to review my research record while the research is ongoing?
No. We are not able to share information in the research records with you until the study is over. To ask for this information, please contact the principal investigator, the person in charge of this research study.

Do I have to give my permission?
No. You do not have to permit use of your information. But, if you do not give permission, you cannot take part in this research study. (Saying no does not stop you from getting medical care or other benefits that you are eligible for outside of this study.)

If I say yes now, can I change my mind and take away my permission later?
Yes. You may change your mind and not allow the continued use of your information (and to stop taking part in the study) at any time. If you take away permission, your information will no longer be used or shared in the study, but we will not be able to take back information that has already been used or shared with others. If you say yes now but change your mind later for use of your information in the study, you must write to the principal investigator and tell him of your decision: Elliot J. Coups, PhD, Rutgers Cancer Institute of New Jersey, 195 Little Albany Street, New Brunswick, NJ 08903.

How long will my permission last?
There is no set date when your permission will end. This is because the information obtained in the study may be analyzed for many years, and it is not possible to know when this will be complete.

AGREEMENT TO PARTICIPATE

1. Subject consent:

I have read this entire form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form or this study have been answered. I agree to take part in this research study.

Subject Name:_____

Subject Signature:_____ Date:_____

2. Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed the full contents of the study including all of the information contained in this consent form. All questions of the research subject and those of his/her parent or legally authorized representative have been accurately answered.

Investigator/Person Obtaining Consent (printed name):_____

Signature:_____ Date: _____