You Are Being Asked to Be in a Research Study

Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study you will be one of 400 people who are being studied, at the American Cancer Society.

Why is this study being done?

This study is being done to answer the question: does the HEALED Physical Activity website increase physical activity? And does increasing physical activity improve sleep, cognitive function, feelings of tiredness, or anxiety in cancer survivors? You are being asked to be in this research study because your information will help researchers better understand how to encourage active living and, eventually, to better understand the benefits of physical activity for cancer survivors.

Do you have to be in the study?

It is your choice to join this research study. You do not have to be in it. Your choice will not affect your continued participation in the CPS-3 cohort or prevent your participation in future ACS studies. Before you choose, take time to learn about the study.

What do you have to do if you choose to join this study?

If you qualify and choose to join the study, you will participate for 12 months (1 year). If you choose to join, you will be randomly placed into one of two groups: one focused on increasing physical activity and one focused on improving balance and flexibility. Each group will have access to different websites. It is not yet clear if the websites can increase physical activity or balance and flexibility. For this reason, your group (Physical Activity OR Balance & Flexibility) will be assigned to you using a method called randomization. Randomization means you will be randomly 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 the Physical Activity or the Balance & Flexibility group.

Both groups will be expected to visit their website regularly and participate on the website by watching videos, over a one-year period. Both groups will also be provided a Fitbit free of charge, to keep. The Physical Activity group participants will be encouraged to wear the Fitbit on their wrist to keep track of their own physical activity and sitting time. The Physical Activity group will also receive occasional motivational e-mails. Both groups will be asked to complete surveys before the study (“baseline”), 3-months into the study, 6-months into the study, and

after the one-year study ("post- study"). During each of these timepoints, you will also be asked to wear an accelerometer (an activity monitor worn around your waist) while awake over a seven-day period. ALL of these procedures will be paid for by the study.

How is this study going to help you?
If you are in the study, you will be helping the researchers answer the study question. The materials on the Physical Activity group website are designed to help cancer survivors be more physically active, and the materials on the Balance and Flexibility group website are designed to help cancer survivors improve their balance and flexibility. Whether they are actually helpful has not been proven yet.

What are the risks or discomforts you should know about before deciding?
The study is one-year long. All studies have some risks. Some risks are relatively small, like being uncomfortable with physical activity or increasing flexibility. Some are more serious. Risks for this study include:

- Muscle fatigue
- Loss of privacy
- Breach of confidentiality

For more information, please visit these two sections of this document: "What are the possible risks and discomforts?" and "How will your private information be protected?".

Alternatives to Joining This Study
Since this is not a treatment study, the alternative is not to participate.

Costs
There will be no costs to you for participating in this study. You will not be charged for any of the research activities.

What Should You Do Next?
Read this form, or have it read to you. Ask questions such as how much time you will have to spend on the study, any words you do not understand, and more details about study procedures. Take time to think about this and talk about it with your family and friends.

Emory University
Consent to be a Research Subject

Title: Health and Energy through Active Living Every Day after cancer: The HEALED study for cancer survivors in the Cancer Prevention Study-3

IRB #: IRB00059007

Principal Investigator: Erika Rees-Punia, PhD, MPH

Sponsor: American Cancer Society

Introduction
You are being asked to volunteer for a sub-study of the Cancer Prevention Study-3 (CPS-3) conducted by the American Cancer Society (ACS). This form is designed to tell you everything you need to think about before you decide if you want to consent (agree) to be in the sub-study or not to be in the sub-study. **It is your choice. If you decide to take part, you can change your mind later and leave the sub-study.**

Before you decide:
- Read this form or have it read to you
- Ask questions about anything that is not clear

You will get an electronic copy of this consent form to keep. Take your time to think about joining the study. Do not electronically initial this form if you still have questions or something does not make sense to you. By electronically initialing this form, you will not give up any legal rights.

A description of this clinical trial will be available on http://www.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 is the purpose of this study?
The purpose of the HEALED After Cancer study is to learn how to help cancer survivors be more physically active. By testing the effect of the HEALED website on physical activity in cancer survivors, we can learn how to best promote active living and, eventually, better understand the benefits of physical activity for cancer survivors.

What will you be asked to do?
This study will have two groups: one focused on increasing physical activity and one focused on improving balance and flexibility. The Physical Activity (PA) group will have access for one year to a website to help increase aerobic and strength training physical activities. The Balance & Flexibility (BF) group will have access for one year to a website to help improve balance and flexibility. At the end of the one-year study, each group will get access to the opposite website (for example, if you are assigned to the PA group and remain in the one-year study, you will also be granted access to the BF group after the study concludes). Both groups will be expected to visit the website regularly and participate in the website's offerings. Both groups will also be provided a Fitbit free of charge, to keep. The Physical Activity group participants will be expected to set physical activity goals through the website and track their goal progress by wearing the Fitbit on their wrist. The PA group will also receive occasional e-mails for motivation.

It is not yet clear if the PA website can increase physical activity, and it is not yet clear if the BF group can help improve balance or flexibility. For this reason, your group (Physical Activity or Balance & Flexibility) will be assigned to you using a method called randomization. Randomization means you will be randomly 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 the PA or the BF group.

Both groups will be asked to complete the same surveys before the study ("baseline"), 3-months into the study, 6-months into the study, and after the one-year study ("post- study"). During each of these timepoints, you will also be asked to wear an accelerometer (an activity monitor worn around your waist) while awake over a seven-day period. For each of the seven days you wear the accelerometer, you will be asked to record the time you woke up and went to bed as well as the time you put on and took off the accelerometer. Detailed instructions on how to wear the device will be provided to you at the start of the seven-day period. At the same time, you will be asked to complete a survey through the CPS-3 participant portal related to your energy, fatigue, ability to think, feelings of depression or anxiety, and sleep quality.

Who owns your study information?

If you join this study, the study information you provide are a donation to the American Cancer Society, and you will not have any property rights nor be entitled to compensation for any use, products, data, or other items or information that is developed from the data. Nevertheless, you may, at any time, request that the American Cancer Society destroy your information, and the American Cancer Society will make all reasonable attempts to honor your request.

What are the possible risks and discomforts?

There may be side effects from the study procedures that are not known at this time. The most common risks and discomforts expected in this study are: You may experience some discomfort with increasing physical activity or flexibility, for example, your muscles may feel sore or tired.

The less common risks and discomforts expected in this study are: There is a small chance that you could become injured while exercising.

Rare but possible risks include: The risk of serious physical activity-related events, including the development of ventricular arrhythmia, myocardial infarction, cardiac arrest, and death, is extremely small. In fact, these risks are no greater than the risk involved in many activities of daily life. Further, the physical activity performed for this study can be done at your comfort level. Research has taught us that being inactive carries far more risks than exercise, even among those with chronic illnesses (such as cancer). However, if a medical doctor or other healthcare professional has told you not to exercise, you should not participate in this research study.

Although strict security measures are in place, there is a potential risk of loss of confidentiality of data collected, including survey data and data collected by Fitbit. Data collected by Fitbit is stored on the device company's server and owned by the company. We will collect data from the Fitbit including steps, active minutes, and sleep time; the devices being used for this study do not have a GPS in the device and do not track location. A company called TADigital built the HEALED website, but they will not have access to any of your personal or health information, as none of this information will be entered into the HEALED website. The HEALED website will be tied to your HEALED Study ID and will only include information about your physical activity goals, your daily active minutes, and any discussion board posts you may write.

Will you benefit from the study?

The HEALED Physical Activity website materials in this study are designed to help cancer survivors be more physically active, and the Balance & Flexibility website materials are designed to help cancer survivors improve their balance and

flexibility. Whether they are actually helpful has not been proven yet. Although you may not personally benefit from taking part in this study, the knowledge gained may benefit others and aid in the design of future interventions. The study results will be used to help better understand how to help cancer survivors be more physically active.

Will you be paid for your time and effort?

You will be provided a monetary incentive for returning your completed study materials at all four time points. You will be compensated for returning your baseline survey ($5) and accelerometer ($10), your 3-month survey ($10) and accelerometer ($15), your 6-month survey ($10) and accelerometer ($15), and your post-study survey ($15) and accelerometer ($20)-- for a possible total of $100 paid out after the one-year study. Additionally, you can keep your Fitbit. If you would like to donate the monetary compensation back to American Cancer Society, that is your choice.

What are your other options?

Your participation in this sub-study is completely voluntary, and you have the right to refuse to join the sub-study. You can stop at any time after giving your consent. Participation is voluntary and failure to participate will not adversely affect you and will not affect your participation in the overall CPS-3 study. You may request that your information be destroyed at any time, simply by contacting the Principal Investigator (Erika Rees-Punia, PhD, MPH, Erika.rees-punia@cancer.org).

How will your private information be protected?

Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results. There are safeguards in place to prevent the unintentional disclosure of information obtained for or produced by this study. Research data provided on the CPS-3 participant portal will be stored temporarily on a secure cloud-based server owned by QuestionPro, Inc., who has a legal contract with the American Cancer Society to provide this service. QuestionPro is compliant with the Department of Commerce policies regarding the collection and retention of personal information. Information will then be moved and stored on ACS' secure Microsoft Azure cloud-based server with limited staff access. The operating systems on the server are updated with the latest patches and issue maintenance releases on a monthly basis, and the ACS server administrator provides access privileges only to required staff who have signed confidentiality agreements and undergone biomedical ethics training.

The accelerometer will not include any personal identifying information other than your HEALED identification number. Once given access to your assigned HEALED website, you will be given a user profile. The username will be your HEALED identification number, but you will be given the choice to change your username (also known as your screen name) if you wish. This name will be seen only by researchers and fellow participants of the study. We advise that you not give any personal identifying information as your screen name to protect your confidentiality.

Analytic data (used by researchers) will be de-identified except for an ID which is used to link a variety of data together. If information about you is published, it will be written so that you cannot be recognized. We may share some research data with other scientists, but these data will not be labeled with any demographic information that personally identifies you. The online portal will be a secure website with login requirements that will only be available to study-participants. All communication on this secure online portal will be done using a username and password that you have created to protect your confidentiality.

Agencies that make rules and policies about how research is done have the right to review research records. Those with the right to look at your study records include the Emory University Institutional Review Board. We will do everything we can to keep others from learning about your participation in the research. To further help protect your privacy, the investigators have obtained a Confidentiality Certificate.

Certificate of Confidentiality

There is a Certificate of Confidentiality from the National Institutes of Health for this study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. The American Cancer Society will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if the American Cancer Society received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop the American Cancer Society from making the following disclosures about you:

- Giving state public health officials information about certain infectious diseases,
- Giving law officials information about abuse of a child, elderly person or disabled person.
- Giving out information to prevent harm to you or others.
- Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

Storing and Sharing your Information

We will store all the data that you provide using a study ID, or a code. We need this code so that we can keep track of your data over time. This code will not include information that can identify you (identifiers). Specifically, it will not include your name, initials, date of birth, or medical record number. We will keep a file that links this code to your identifiers in a secure location separate from the data.

We will not allow your name and any other fact that might point to you to appear when we present or publish the results of this study.

Your data may be useful for other research being done by investigators at Emory or elsewhere. We may share the data linked by the study code, with other researchers at the American Cancer Society, or with researchers at other institutions that maintain at least the same level of data security that we maintain at ACS. We will not share the link between the study code and your identity.

Returning Results to Participants/Incidental Findings

We will not give you any individual results from the study.

In Case of Injury

If you believe you have become injured from this research, you should contact Dr. Rees-Punia at telephone number 404-982-3684. You may choose to let any health care provider who treats you know that you are in a physical activity research study.

If you get injured from being in the study, neither Emory nor the sponsor have set aside money to pay for this medical treatment. Your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurance does not pay, then you will have to pay these costs.

Costs
There will be no costs to you for participating in this sub-study. You will not be charged for any of the research activities.

Withdrawal from the Study
You have the right to leave a study at any time without penalty.

Participation in this sub-study is completely voluntary, and you have the right to refuse to join the sub-study. You can stop at any time after giving your consent. Failure to participate will not adversely affect you and will not affect your participation in the overall CPS-3 study. You may request that your information be destroyed at any time, simply by contacting the Principal Investigator (Erika Rees-Punia, PhD, MPH, Erika.rees-punia@cancer.org).

If you leave the sub-study before the last planned data collection, the researchers may ask you to complete some of the final steps such as returning study devices as applicable.

The researchers also have the right to take you out of the sub-study without your consent for any reason. They may do this if they believe it is in your best interest.

These are some other reasons why the researchers may take you out of the study:

- You sustain an injury
- You are diagnosed with a new cancer
- You become pregnant

Contact Information
If you have questions about the study procedures, appointments, research-related injuries, or other questions or concerns about the research or your part in it, contact Erika Rees-Punia at 404-982-3684 or Erika.rees-punia@cancer.org.

This study has been reviewed by an ethics committee to ensure the protection of research participants. If you have questions about your **rights as a research participant**, or if you have **complaints** about the research or an issue you would rather discuss with someone outside the research team, contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu.

To tell the IRB about your experience as a research participant, fill out the Research Participant Survey at **https://tinyurl.com/ycewgkke.**

Consent
By electronically initialing this consent form, you will not give up any of your legal rights. A copy of the informed consent will be available in the "Documents" page in your secure portal.

I have read this consent form. My questions have been answered. By checking "I Agree", typing my initials in the box below and clicking "Done", I am providing consent to join this sub-study. I consider this consent form valid for the duration of my participation in the CPS-3 HEALED After Cancer Sub-Study.