The University of New Mexico Health Sciences Center

Consent and Authorization to Participate in a Research Study

Key Information: ***Move for Your Health (MY Health) Study***

You are being invited to take part in a research study that will test whether a Fitbit activity tracker can help cancer survivors be more active throughout the day.

What Is The Purpose, Procedures, And Duration Of The Study?

Staying active is a key factor in aging. Being active enables us to do the activities we enjoy. Using a fitness tracker may help people to move around more, whether or not they choose to exercise. Moving more could improve health and quality of life. The **MY Health Study** will test whether a Fitbit® activity tracker can help cancer survivors be more active throughout the day. The study will provide a Fitbit activity tracker. A Health Coach will provide guidance and support throughout the study. Your participation in this research will last 26 weeks (6 months). Approximately 64 cancer survivors from New Mexico will take part in this study.

What Are The Main Reasons To Join This Study?

There may be possible benefits to your health and quality of life through becoming more active. You may take pride in contributing to research designed to promote better health and well-being in cancer survivors throughout New Mexico. Refer to the Detailed Consent for additional benefits.

What Are The Main Reasons Not To Join This Study?

You may experience some inconvenience with participation in this or any research study. For a complete description of the risks, refer to the Detailed Consent.

Do I have to join this study?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

What If You Have Questions, Suggestions Or Concerns?

The person in charge of this study is Dr. Cindy Blair of the University of New Mexico Health Sciences Center, Department of Internal Medicine. If you have questions, suggestions, or concerns about this study or you want to leave the study, you may call Dr. Blair at 505-925-7907 or email to CiBlair@salud.unm.edu.

If you have any questions or concerns about your rights as a volunteer in this research, contact staff in the University of New Mexico Health Sciences (UNMHSC) Human Research Review Committee (HRRC) between 8AM and 5PM, Mountain Standard Time (MST), Monday-Friday at 505-272-1129.

Who Can Join The Study?

You can be part of this study if you: (1) are 65 years or older; (2) have or had a cancer diagnosis; and (3) exercise less than 30 minutes each day on most days of the week.

Where Is The Study Going To Take Place?

The study takes place where you live – your home, your neighborhood, and wherever you choose to go. Surveys will be mailed to your house. You will complete other study procedures at your home.

What Will I Be Asked To Do?

If you agree to be in this study, you will be asked to read and sign this Consent Form. We will ask you to do the following:

- **Assessments:** We will ask you to complete three assessments during the study: at the beginning of the study, at week 13, and at week 26. You will receive a packet in the mail that includes the following:
  - *An activity monitor:* We will ask you to wear an activity monitor for 7 days. The small, thin device (like a patch) will be worn on your leg (day and overnight). This is not a tracking device and we will not be able to tell the specific activity that is happening. Instead, the monitor will record general movement and allows us to get a better idea of your daily activity level. Instructions are provided for applying and removing the monitor.
  - *Surveys*: to assess your health, lifestyle behaviors, and quality of life. You can also complete the surveys online.
  - *Instructions for returning study materials*
  - *Envelope with pre-paid postage for returning study materials*

  After you have received the packet, a member of the study team will telephone you to answer your questions and help you put on your activity monitor. A day and time will be scheduled for your physical function tests.

  Physical function tests: You will receive instructions on how to safely conduct the physical function tests and how to communicate with the study team using videoconferencing software (example: Zoom or Skype). You will be completing two timed tests - 1st: you will be asked to stand in four (4) different positions for 10 seconds each (for example, feet side-by-side, one foot behind the other, standing on one foot); 2nd: you will be asked to stand up from a chair without using your arms and sit back down again, and to repeat this for 30 seconds. **You must have a friend or family member present for this portion of the study**. These video calls will be recorded for quality control. These video recordings will be destroyed 3 years after the study closes.

- **Next, we will assign you to 1 of 2 groups:**

  Group A:

  If you are in this group, we will ask you to do these things from week 1 through 12:

  - Wear a Fitbit activity tracker on your wrist during the day, every day. The tracker and cell phone app (application) will help you increase your activity throughout each day.
  - Sync your Fitbit tracker with your smartphone at least 3 times each week. We will help you to set this up. If you do not have a mobile phone, we can lend you one for the study (you will have to return it in week 26).
  - Talk regularly with one of our health coaches. There are 6 calls to assist you with using the tracker, installing the app on your cell phone, fixing any technical problems that may occur and providing you with guidance and support to help you meet your activity goals. These calls will be audio recorded for quality control. These audio recordings will be destroyed 3 years after the study closes.

  Then, from weeks 13 through 26, you will continue to wear the Fitbit, but will not receive support from your health coach.

  Group B:

  If you are in this group, we will ask you to maintain your usual activity from week 1 through week 12. Then after you have completed your second assessment in week 13, we will ask you to do these things from weeks 13 through 26:

  - Wear a Fitbit activity tracker on your wrist during the day, every day. The monitor and cell phone app (application) will help you increase your activity throughout each day.
  - Sync your Fitbit tracker with your smartphone at least 3 times each week. We will help you to set this up. If you do not have a mobile phone, we can lend you one for the study (you will have to return it in week 26).
  - Talk regularly with one of our health coaches. There are 6 calls to assist you with using the tracker, installing the app on your cell phone, fixing any technical problems that may occur and providing you with guidance and support to help you meet your activity goals. These calls will be audio recorded for quality control. These audio recordings will be destroyed 3 years after the study closes.

  Note: Regardless of the group that you are assigned to, the Fitbit activity tracker and mobile phone app are yours to keep when the study is over, at no cost to you.

- Post-Study Telephone Survey: Your opinion about the study is very important to us. At the end of the study, a member of the study team will telephone you to ask you what you liked and didn't like about being in the study, and what you would suggest to improve the study.

How Long Will I Be In This Study?

Participation in this study lasts for 26-weeks (6-months). The assessments will take approximately one hour each. The first two health coaching calls may take up to 45 minutes; the other calls will take up to 20 minutes each. There are six calls over the 12 weeks. The Post-

Study Telephone Survey will take no longer than 20 minutes. The estimated time for participation in this study is less than 7 hours over the next 6-months.

What Are The Possible Risks Or Discomforts Of Being In This Study?

As with any research study, there may be unforeseen risks. Every effort is made to protect the information you give us. However, there is a small risk of loss of privacy and/or confidentiality that may result in emotional distress or inconvenience.

While we are taking necessary precautions to ensure your safety during your assessment, there is a slight risk for physical injury that could occur during physical function testing.

There is a slight risk of skin irritation on your leg due to the adhesive used to attach the leg activity monitor. If irritation occurs, you will be asked to remove the monitor and clean the area with soap and water.

Other risks to participate in this study are no greater than the risks of day-to-day living. However, if you do experience any discomfort or negative feelings associated with participation, Dr. Cindy Blair, the lead investigator of the study will be glad to discuss them with you. Dr. Blair can be reached at (505) 925-7907 or CiBlair@salud.unm.edu.

Will I Benefit From Talking Part In This Study?

There may or may not be direct benefit to you from being in this study. However, there may be possible benefits to your health and quality of life by becoming more active. Also, your participation may help us to better understand ways to promote better health and well-being in cancer survivors.

What Will It Cost To Participate? Will I Be Paid For participating In This study?

There is no cost to you for participating in this study. To compensate you for your time and participation in the study (including cell phone charges for accessing the phone app), you will receive a total of three merchandise cards ($50 each) after completion of each of the three home-based assessments. The Fitbit activity tracker is yours to keep after the study ends (a $99 value).

If you earn $600 or more by participating in research, it is potentially reportable for tax purposes.

Who Will See The Information That I Give?

When we write about or share the results from the study, we will write about the overall information. We will always keep your name and other identifying information private.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave information, or what the information is. Your name and other identifying information will be stored in locked files, available only to key members of the research team, for the duration of the study. For any information entered onto a computer, the only identifier will be a unique study identification (ID) number. Any personal identifying information and any record linking that information to study ID numbers will be destroyed 4 years beyond the end of the study. This will allow the study team the necessary time to complete the analyses of all the collected data.

You should know there are some circumstances in which we may have to show your information to other people who provide regulatory and ethical oversight of human research. Examples include the UNM Human Research Review Committee (HRRC) and the UNM Comprehensive Cancer Center Data Safety & Monitoring Committee. Also, the law may require us to share your information for the following reasons:

- Cases of diseases that spread easily (example: measles)
- Abusive behavior (toward a child, a partner, or an elderly person)
- People who say they are going to hurt themselves or someone else
- Information for auditing or program evaluation by the funding agency

REDCap is a secure, web-based program to capture and store data at the University of New Mexico. Please be aware, while we make every effort to safeguard your data once received on servers via REDCap, given the nature of online surveys, as with anything involving the internet, we can never guarantee the confidentiality of the data while still in route to the server.

Fitabase is a research platform that captures and stores data from your Fitbit device. Data collected includes total daily steps, steps per minute, estimated energy expenditure, distance walked, minutes of vigorous, moderate, and light activity, minutes of sedentary time, sleep length, quality, and movement, heart rate, and manually entered and automatically detected physical activities such as walking or running. At the end of the study, we will disconnect your Fitbit account from Fitabase. No personal information is stored in either your Fitbit account or in Fitabase.

Can You Choose To Withdraw From The Study Early?

You can choose to leave the study at any time. You will not be treated differently if you decide to stop taking part in the study.

If you choose to leave the study early, data collected until that point will remain in the study database and may not be removed.

The investigators conducting the study may need to remove you from the study. You may be removed from the study if the investigators determine that:

- You no longer qualify to take part
- You are not able to follow the directions
- Participation in the study is more risk than benefit to you

Can You Take Part In Other Studies While You Are In This One?

You may not take part in this study if you are currently involved in another research study focused on increasing physical activity. It is important to let the investigator know if you are in another research study.

What Happens If I Get Injured Or Sick During The Study?

If you are hurt or become sick from taking part in this study, you should call Dr. Cindy Blair at 505-925-7907 immediately.

It is important for you to understand that the University of New Mexico does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt

or sick while taking part in this study. Also, the University of New Mexico will not pay for any wages you may lose if you are harmed by this study.

Medical costs related to your care and treatment because of study-related harm should be sought from your insurer, managed care plan, or other benefits program. If you do not have insurance, you may be responsible for these costs. You will also be responsible for any associated co-payments or deductibles required by your insurance.

Will I Be Given Individual Results From The Research Tests?

Generally, tests and other data collected for research purposes are not meant to provide clinical or other information to the study participant. Therefore, individual results will not be returned. However, if at the end of the study, you would like to know the results of your physical function tests or other measurements, please contact Dr. Blair (505-925-7907) or her Project Manager (505-274-8596).

The National Cancer Institute and the University of New Mexico Comprehensive Cancer Center are providing financial support for this study.

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 any time.

Future Use Of Your Protected Health Information.

Your information collected for this study will not be used or shared for future research studies, even if we will remove the identifiable information like your name or date of birth.

Health Insurance Portability Authorization Act (HIPAA) For Use And Disclosure Of Your Protected Health Information (PHI)

As part of this study, we will be collecting health information about you. This information is "protected" because it is identifiable or "linked" to you.

Protected Health Information (PHI)

By signing this Consent Document, you are allowing the investigators and other authorized personnel to use your protected health information for the purposes of this study. This information may include demographic information (your name, where you live, phone number, e-mail address, etc.), information about your cancer diagnosis (type of cancer, year of diagnosis, type of treatment(s)), information from surveys (medical history, lifestyle behaviors, etc.), and information from physical function tests and the physical activity monitor.

In addition to researchers and staff at UNMHSC and other groups listed in this form, there is a chance that your health information may be shared (re-disclosed) outside of the research study and no longer be protected by federal privacy laws. Examples of this include disclosures for law enforcement, judicial proceeding, health oversight activities and public health measures.

Right to Withdraw Your Authorization

Your authorization for the use and disclosure of your health information for this study shall not expire unless you cancel this authorization. This is because the information used and created during the study may be analyzed for many years and it is not possible to know when this will be complete. Your health information will be used as long as it is needed for this study. However, you may withdraw your authorization at any time provided you notify the UNM investigators in writing. To do this, please send a letter notifying them of your withdrawal to:

Cindy Blair, PhD
MSC 11-6020
1 University of New Mexico
Albuquerque, New Mexico 87131

Please be aware that the research team will not be required to destroy any of your health information that has already been used or shared before the date your withdrawal is received.

The researchers agree to only share your health information with the people listed in this document. Should your health information be released to anyone that is not regulated by the privacy law, your health information may be shared with others without your permission; however, the use of your health information would still be regulated by applicable federal and state laws.

You may not be allowed to participate in the research study if you do not sign this form. If you decide not to sign this form, it will not affect your:

- Current or future healthcare at the University of New Mexico;
- Current or future payments to the University of New Mexico;
- Ability to enroll in any health plans (if applicable); or
- Eligibility for benefits (if applicable).

After signing the form, you can change your mind and NOT let the researcher(s) collect or release your health information (revoke the Authorization). If you revoke the authorization:

- You will send a written letter to Dr. Cindy Blair at MSC11-6020; One University of New Mexico; Albuquerque New Mexico 87131 to inform her of your decision.
- Researchers may use and release your health information already collected for this research study.

You understand that you will not be allowed to review the information collected for this research study until after the study is completed. When the study is over, you will have the right to access the information.

The use and sharing of your information have no time limit.

If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions about your privacy rights, you should contact the University of New Mexico Health Sciences Privacy Officer between the business hours of 8am and 5pm Mountain Time, Monday-Friday at (505) 272-1493.

INFORMED CONSENT SIGNATURE PAGE

You are the participant or are authorized to act on behalf of the participant. This consent includes the following:

- Key Information Page
- Detailed Consent and HIPAA

You will receive a copy of this consent form after it has been signed.

_____ _____

Signature of research participant **Date**

_____

Printed name of research participant

_____ _____

Printed name of study personnel obtaining informed consent/HIPAA Authorization **Date**

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Signature of study personnel obtaining informed consent/HIPAA Authorization