CONSENT FORM

Exercise Intervention for Cancer Survivors and Caregivers

Principal Investigator: Charles Kamen, Ph.D.

This consent form describes a research study, what you may expect if you decide to take part, and important information to help you make your decision. Please read this form carefully.

The study staff will explain this study to you. Please ask questions about anything that is not clear before you agree to participate or at any time. You may take this consent form home to think about and discuss with family or friends.

Because we are asking people who have been treated for cancer as well as their caregivers to participate in this study, we will use the word "partner" throughout this consent form. "Partner" means the other person participating in this study with you, either a person who was treated for cancer or your caregiver.

- Being in this study is voluntary – it is your choice.
- If you join this study, you can change your mind and stop at any time.
- If you choose not to take part, neither your medical care nor your partner's medical care will be changed in any way.
- There are risks from participating and you should understand what these mean to you.

Introduction

You are being asked to take part in this study either because you were diagnosed with cancer and received treatment for cancer, or because you provided care (emotional support, medical assistance, or other forms of care) to someone who received treatment for cancer. In this form, we will call people who received treatment for cancer "*cancer survivors*," and we will call people who provided care for someone receiving treatment for cancer "*caregivers*."

This study is being conducted by Dr. Charles Kamen, a psychologist working in the University of Rochester's Department of Surgery-Cancer Control.

Background

Cancer can cause symptoms of anxiety and depression in both cancer survivors and their non-professional caregivers (i.e., spouses, family or friends providing support, tangible assistance or emotional encouragement to cancer survivors). Exercise has been shown to reduce anxiety and depression in cancer survivors. However, very few studies to date have delivered an exercise intervention to cancer survivors and their caregivers together and few studies have focused on minority and underserved groups, such as sexual minorities, men who partner with men, women who partner with women, and gender minorities (that is, LGBT patients).

In a smaller study, we tested an exercise intervention called EXCAP©® (Exercise for Cancer Patients). We are now conducting a larger study, where we are specifically testing EXCAP©® for survivors and their caregivers with a focus on minority and underserved groups as described above. In this six-week long intervention, participants are instructed to increase the number of steps they walk each day and also instructed to perform a series of strength training exercises each day.

Purpose of Study

The purpose of this study is to see whether exercise can improve the health and well-being of cancer survivors. We also want to know about the health and well-being of caregivers.

Description of Study Procedures

If you decide to take part in this study, you will be asked to do a number of things, listed below.

1. Screening and Baseline Visit

We will first need to confirm that you are medically ready to be exercising. We will ask you some questions about your health, and we will ask to contact your physician to get his/her approval for you to begin an exercise program.

We will also review your medical record to identify information about your cancer, the type of treatments you are receiving, and medical conditions and laboratory data that have been obtained by your doctors.

Once we are sure about your medical readiness, we will ask you to come to the University of Rochester PEAK Lab two times. The first time will be before the study begins, and the second time will be about six weeks later, when the study is over. The procedures for each visit will include the following:

1. If you decide to be a part of this study, at the end of this meeting, we will give you a pedometer and a special kind of monitor called an Actigraph. Before you come to the PEAK Lab for your baseline assessment, we will contact you via phone or e-mail and ask you to wear the pedometer and actigraph for seven days. The pedometer will tell us how many steps you are walking on an average day, and the actigraph will tell us how physically active you are. We will collect the pedometer and actigraph when you come to the PEAK Lab.

2. We will ask you to have a fasting blood draw (around 2 tablespoons) taken after you have not eaten for approximately 8 hours. This will allow us to measure biomarkers, which include proteins in the blood that make up the body's immune response. This measurement will be done before your fitness testing. You will be offered breakfast or a snack afterwards. Your blood will be drawn in the General Clinical Research Center, which is right above the PEAK Lab, or your blood will be drawn at a regularly scheduled clinic visit.

   With your permission, we would like to keep some of your blood for future research to identify markers of side effects of cancer and treatment, as well as your response to exercise. If you don't want your blood used for future research purposes, you can still be in the study. You can let us know if you agree to the use of your blood samples for future research by checking the appropriate space at the end of this form. These samples will not contain information that identifies you, and only the researchers will be able to link you with your sample. Sometimes future research will use samples for genetic research (about diseases that are passed on in families). If a genetic study is being done, DNA (inherited material) will be isolated from the sample. A variety of tests may be used to examine the genes we think may be related to your disease or condition. The exact testing that will be done is not known at this time, so we cannot give you more details right now. Even if your sample is used for this kind of research, the results will not be put in your health records. However, because your genetic information is unique to you, there is a small chance that someone could trace it back to you. The risk of this happening is small, but may grow in the future. Researchers have a duty to protect your privacy and to keep your information confidential. There is a federal law called the Genetic Information Non-Discrimination Act, or GINA to help protect you. This law helps to lower the risk of health insurance or employment discrimination. The law does not include other types of misuse by life insurance or long term care insurance. To learn more about the GINA Law, please ask the study staff or check the

internet. Records about you and the genetic testing results will be kept in a coded fashion. We may need to contact you to obtain your consent to future genetic testing of your samples.

3. We will ask you to fill out computerized questionnaires that ask basic information about your medical history, mood, fatigue, quality of life, depression, anxiety, sleep, stress, and physical activity. These forms will take approximately 30 minutes to complete.

4. We will ask you to complete the following fitness evaluations:
    a. A measure of your heart rate. You will wear a heart rate monitor while sitting quietly in the PEAK Lab for five minutes.

    b. A hand grip test, a leg extension test, and a shoulder pull-down test, all three of which measure muscular strength. These tests combined will take about 30 minutes.

    c. Bioelectrical impedance analysis (BIA), which measures your amount of body fat, muscle, and other lean tissue by sending a small painless electrical current through your body. The procedure involves placing electrodes (wires with stickers), like the ones used for an EKG, on the right hand and foot. You will need to lie still while the measurement is taken. This will take about 5 minutes.

    d. A 6 minute walking test will also be completed. You will be given a short warm up walking period in the test walking area in the PEAK Lab. Then you will walk for a total of 6 minutes and cover as much distance as you can during this time. After the test, you will be allowed to cool down. Upon completion of the test, the total distance walked will be used to calculate your cardiovascular fitness.

We estimate that your baseline assessment will take approximately 2-3 hours. We will accommodate your schedule as best as we can.

The following information about your study participation will be included in your electronic health record:

- Documenting you are in this study
- A copy of your signed consent form

2. Six Week Exercise Program

After completing the baseline measures, <u>you will be assigned at random (by chance using a computer) to one of two study groups for the six-week study period.</u> We will either ask the cancer survivor and caregiver to exercise together (Group 1), or we will ask the cancer survivor

to exercise alone and the caregiver to keep his/her behavior the same (Group 2). All groups will receive standard care monitoring.

As part of the study group to which you are randomized, you or your partner may be told how to do certain exercises. If so, you will be given a kit to help you complete these exercises. Explaining how to do the exercises will take about 45 minutes. At the end of the study, everyone will be given an exercise kit. During the study, you will be asked to complete a daily diary that asks about exercise and about your symptoms.

3. Post-Exercise Visit

After exercising for six weeks, you will again be asked to wear the pedometer and actigraph for 7 days. You will then return to the PEAK Lab for a second assessment. The second assessment will be exactly like the baseline and will involve: 1) a fasting blood draw, 2) filling out questionnaires, and 3) a fitness evaluation. As in the baseline assessment visit, your post-exercise visit will take approximately 2-3 hours. We will make every attempt to accommodate your schedule.

So, in total, you will be asked to come to the PEAK Lab two times, about six weeks apart. Each visit to the PEAK Lab will take about three hours. You will be asked to wear a pedometer and an actigraph for seven days before coming to the PEAK Lab, and you may be asked to do some exercises in between visits. You will be asked to complete a daily diary that asks about exercise and about your symptoms. A member of the study team will contact you each week to check in and remind you of your next visit.

Number of Subjects

Approximately 140 people will take part in this study, in 70 pairs of cancer survivors and caregivers.

Duration of the Study

Your participation in the study will last for about seven or eight weeks total. You will wear a pedometer and actigraph for seven days, come to the PEAK Lab for a two to three hour visit, wait for six weeks, wear the pedometer and actigraph for another seven days, and then come back to the PEAK Lab for one last two to three hour visit.

Risks of Participation

Starting a moderate walking and resistance exercise program is not associated with any serious risks. Risks of exercise in general are very low for individuals with no heart-, lung-, bone-, or age-related medical problems, as determined by a physician. For example, one adult per year for every 15,000 to 18,000 people suffers a heart attack while engaging in vigorous exercise. Although unlikely, the risks involved in a moderate walking and progressive resistance exercise program include muscle cramps, muscle strain and/or joint injury, delayed

muscle soreness, lightheadedness, and fatigue. An increase in blood pressure may occur with all types of exercise. Overall, the risk level for participation in the moderate intensity EXCAP Home-Based Walking and Progressive Resistance program is minimal.

Risks associated with a 6 minute walk test are similar to participation in a moderate to vigorous walking exercise program and are minimal for individuals with no risk factors as determined by a physician. Risks include muscle cramps, muscle strain and/or joint injury, delayed muscle soreness, lightheadedness, and fatigue. Leg and shoulder tests for strength may cause minor stiffness and/or tenderness in muscles for a couple of days following testing. The nature of these assessments will require a level of exertion; this exertion may cause temporary changes such as an increase in heart rate and blood pressure, both of which are normal responses to moderate exercise.

There is a small risk of irritation to the skin from the electrodes used for the BIA analysis.

Every effort will be made to minimize the risks for all study procedures. We will ask for the written approval of your physician for each participant before you begin the study. All testing and exercise instruction will be supervised by an American College of Sports Medicine Certified Exercise Physiologist. A physician (or physician's designee) will be present for testing when necessary according to American College of Sports Medicine Guidelines. We will use standardized guidelines for exercise testing and prescription provided by the American College of Sports Medicine and use of trained technicians for the bioelectrical impedance analysis. Electrodes will be removed immediately after the bioelectrical impedance test to minimize skin irritation. Risks will also be minimized by following the documented and approved procedures for blood draws performed in the University of Rochester General Clinical Research Center; trained research nursing staff will perform the blood draw.

Blood drawing may cause pain and bruising at the site where the blood is taken, and sometimes, it causes people to feel light-headed or even to faint. Rarely you might get an infection at the site of the needle stick. This will be minimized through the use of a trained phlebotomist, standardized hospital procedures for blood collection, and sterile materials.

While every effort will be made to keep data collected in the course of this study private, this cannot be guaranteed. Other people may need to see the information. While they normally protect the privacy of your information, they may not be required to do so by law.

The study team may be notified if you receive other health care services at URMC or its Affiliates (e.g., visit to the emergency room). In addition, the following individuals may know you participated in research and may see results of testing conducted for this study:

- Staff at the University of Rochester Medical Center and its Affiliates (e.g., Strong Memorial Hospital, Highland Hospital, URMC primary care, Interlakes, specialist physician offices) who have a reason to access your electronic health record. Individuals who request a copy of information from your health record for activities such as treatment or payment (e.g., medical insurance companies, worker's compensation

Benefits of Participation
You might not benefit from being in this research study.

New Study Findings
If we discover anything that might make you change your mind about continuing in the study, we will let you know.

Costs
There will be no cost to you to participate in this study.

Payments
You will be paid up to $100 for taking part in this study. You will receive $40 for coming to the first visit and $60 for coming to the second visit.

Circumstances for Dismissal
You may be withdrawn from the study if you do not keep appointments for study visits or if you cannot complete study activities, or if we or your physician feel that continuing in the study would negatively affect your health.

Circumstances for Leaving the Study
You may withdraw from the study at any time. You may keep the exercise kit, if one has been given to you, and any payments that have been made to you by the time you withdraw. Neither your medical care nor your partner's medical care will be affected by withdrawal.

Confidentiality of Records
The University of Rochester makes every effort to keep the information collected from you private. In order to do so, we will keep all information you provide to us in locked filing cabinets in a locked office; electronic data will be kept in a password-protected and secure database; and blood samples will be kept in a locked refrigerator in a locked laboratory. Sometimes, however, researchers need to share information that may identify you with people that work for the University or other regulators. If this does happen we will take precautions to protect the information you have provided. Results of the research may be presented at meetings or in publications, but your name will not be used.

Confidentiality of Records and Authorization to Use and Disclose Information for Research Purposes

If you have never received a copy of the University of Rochester Medical Center (URMC) and Affiliates Notice of Privacy Practices, please ask the investigator for one.

What information may be used and given to others?

The study doctor will get your personal and medical information. For example:

- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Past and present medical records related to the study
- Results of medical tests

Who may use and give out information about me?

- The study doctor and the study staff
- URMC and Affiliates

Your information may be given to:

- The Department of Health and Human Services
- The University of Rochester

Why will this information be used and/or given to others?

- To do the research
- To study the results
- To see if the research was done right

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study.

May I review or copy my information?

Yes, but only after the research is over.

How long will this be permission be valid?

This permission will last indefinitely.

May I cancel my permission to use and disclose information?

You may cancel your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. Upon receiving the written notice, the study team will no longer use or disclose your health information and

you will not be able to stay in this study. Information that has already been gathered may need to be used and given to others for the validity of the study.

May I withdraw from the study?

Yes, you may withdraw from the study. If you withdraw your permission to be in the study, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?

No. There is a risk that your information will be given to others without your permission.

A description of this clinical trial will be available on the internet at: 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.

Contact Persons

For more information concerning this research please contact: Dr. Charles Kamen at 585-275-9958 or Nikki Murray, MS at 585-276-4638. If you feel that your participation has resulted in any emotional or physical discomfort or injury, you may contact Dr. Richard Dunne, MD, at 585-275-9484.

Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420628, Rochester, NY 14642, Telephone (585) 276-0005 or (877) 449-4441 for the following reasons:

- You wish to talk to someone other than the research staff about your rights as a research subject;
- To voice concerns about the research;
- To provide input concerning the research process;
- In the event the study staff could not be reached.

Voluntary Participation

Taking part in this study is voluntary. You are free not to take part or to withdraw at any time, for whatever reason. No matter what decision you make, there will be no penalty or loss of benefit to which you are entitled. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner.

After reading and discussing the information in this consent form you should understand:

- Why this study is being done;
- What will happen during the study;

- Any possible risks and benefits to you;
- Other options you may have instead of being in the study;
- How your personal information will be protected;
- What to do if you have problems or questions about this study.

Use of E-mail for Communication in Research

When using e-mail to communicate with you in this study, the researcher cannot guarantee, but will use reasonable means to maintain security and confidentiality of e-mail information sent and received. You and the researcher should understand the following conditions, instructions and risks of e-mail use:

Conditions for e-mail use:

a) E-mail is not appropriate for urgent or emergency situations. The researcher cannot guarantee that any particular e-mail will be read and responded to.
b) E-mail must be concise. You should schedule an appointment if the issue is too complex or sensitive to discuss via e-mail.
c) E-mail communications between you and the researcher will be filed in your research record.
d) Your messages may also be delegated to any member of the study team for response.
e) The researcher will not forward subject-identifiable e-mails outside of URMC and Affiliates without your prior written consent, except as authorized or required by law.
f) You should not use e-mail for communication regarding sensitive medical information.
g) It is your responsibility to follow up and/or schedule an appointment if warranted.

Instructions for e-mail use:

a) Avoid use of your employer's computer.
b) Put your name in the body of the e-mail.
c) Put the topic (e.g., study question) in the subject line.
d) Inform the researcher of changes in your e-mail address.
e) Take precautions to preserve the confidentiality of e-mail.
f) Contact the researcher's office via conventional communication methods (phone, fax, etc.) if you do not receive a reply within a reasonable period of time.

Risks of e-mail use:

Sending your information by e-mail has a number of risks that you should consider. These include, but are not limited to, the following:

a) E-mail can be circulated, forwarded, stored electronically and on paper, and broadcast to unintended recipients.
b) E-mail senders can easily misaddress an e-mail.
c) Backup copies of e-mail may exist even after the sender or the recipient has deleted his or her copy.
d) Employers and on-line services have a right to inspect e-mail transmitted through their systems.
e) E-mail can be intercepted, altered, forwarded, or used without authorization or detection.
f) E-mail can be used to introduce viruses into computer systems.

Optional Storage and Future Use of Blood Samples

As discussed earlier in this consent, we would like to keep some of your blood for future research to identify markers of side effects of cancer and treatment, as well as your response to exercise. If you don't want your blood used for future research purposes, you can still be in the study.

Please check one of the choices below indicating whether you agree or not to the storage and future use of your samples.

☐ I **agree** to the storage and use of my blood samples for future research to identify markers of disease and response to exercise.

☐ I **do not agree** to the storage and use of my blood samples for future research to identify markers of disease and response to exercise.

Contact While on Study

We might need to contact you during your participation on this study. Indicate below how you would like us to contact you.

☐ I **agree** to being contacted via email while in this study.

☐ I **do not agree** to being contacted via email, I prefer to be contacted via phone while in this study.

No additional procedures will be performed after this study is completed; however, we may need to contact you in the future if additional information is needed for purposes of this study. Do you agree to be contacted in the future?

· Yes · No

If you are willing to give information about this study to other people who might be interested in participating, we can provide you with brochures to pass out. We will contact you in the future to see if you need additional brochures. You are under no obligation to give out these brochures. Do you consent to receive brochures and to be contacted about the brochures in the future?

· Yes · No

Signatures/Date

Subject Consent

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I agree to participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

_____

Subject Name (Printed by Subject)

_____ _____

Signature of Subject Date

Person Obtaining Consent

I have read this form to the subject and/or the subject has read this form. I will provide the subject with a signed copy of this consent form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have given the subject adequate opportunity to read the consent before signing.

_____

Name and Title (Print)

_____ _____

Signature of Person Obtaining Consent Date