RUTGERS
Cancer Institute
of New Jersey
RUTGERS HEALTH

HERO Project HERO: Health Empowerment & Recovery Outcomes

CONSENT TO TAKE PART IN A RESEARCH STUDY

TITLE OF STUDY: Project HERO: Project for Health Empowerment & Recovery Outcomes
Principal Investigator: Dr. Anita Kinney

STUDY SUMMARY: This consent form is part of an informed consent process for a research study and 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: determine whether usual care, or a body training program, or a body-mind training program may help improve health and well-being in 166 senior men with a diagnosis of cancer. If you take part in the research, you will be asked to complete a baseline evaluation, be randomly assigned to 1 of 3 groups and complete follow up assessments. Your time in the study will take approximately 15 months. Possible harms or burdens of taking part in the study may be a breach of participant confidentiality and privacy. Every effort will be made to protect the information you give us. The researchers are trained to protect your information and to use procedures that reduce the possibility of loss of privacy and/or confidentiality. It is possible that you may experience some psychological distress specific to coping with a stressful life event such as living with a previous cancer diagnosis. It is also possible that you will experience overall body or joint pain from the physical activity. The risks of injury during blood draw are minimal and include superficial bruises, discomfort and bruising at the site of the needle insertion, bleeding from the site of puncture, and uneasiness associated with needles. There may be risks that are unforeseeable. Possible benefits include interacting with other cancer survivors and receiving free instruction in a gentle form of body-mind exercise or body exercise that may improve your overall quality of life. You may also find satisfaction in contributing to important cancer research. An alternative to taking part in the research study is not to take part in it.

The information in this consent form will provide more details about the research study and what will be asked of you if you choose to take part in it. If you have any questions now or during the study, if you choose to take part, you should feel free to ask them and should expect to be given answers you completely understand. After all of your questions have been answered and you wish to take part in the research study, you will be asked to sign this consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by signing this consent form.

Who is conducting this research study?
Dr. Anita Kinney is the Principal Investigator of this research study. A Principal Investigator has the overall responsibility for the conduct of the research. However, there are often other individuals who are part of the research team.

Dr. Kinney may be reached at 732-235-8545. Her address is:

Anita Kinney, PhD, RN
School of Public Health &
Cancer Institute of New Jersey
195 New Albany Street
New Brunswick, NJ 08901

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 study is funded by a grant from the National Institutes of Health, National Cancer Institute.

Why is this study being done?
You are being invited to take part in a research study that aims to determine whether usual care, or a body training program or a body-mind training program may help improve health and well-being in 166 senior men with a diagnosis of cancer.

Positive mental health among cancer survivors has been shown to protect against physical decline and improve overall well-being.

Who may take part in this study and who may not?
Men 55 and older who have been diagnosed with cancer may take part in this study. Participants should also be able to read and complete study materials in English and have access to reliable transportation to attend clinic visits and classes.

Why have I been asked to take part in this study?
You are being invited to take part in this study because you are a cancer fighter or survivor and 55 years of age or older.

How long will the study take and how many subjects will take part?
The study overall will last 4 years. Your participation in the study will be approximately 15 months. Each survey will take about 45 minutes to complete. The food and activity questionnaire will take about 30-45 minutes to complete. The first clinic visit will take approximately 1 hour to complete. Other clinic visits will take about 45 minutes to complete. If you are randomized into either the body training or body-mind training group, the health classes will occur over the course of 12 weeks and will meet two times a week for one hour. You will be asked to practice what you learn in your health class for 30 minutes a day 3-5 times per week. It will take just a few minutes a day to fill out the physical activity log.

What will I be asked to do if I take part in this study?
If you decide to participate in this research study, you will be asked to do the following:

1. **Complete a baseline evaluation:**
    a. **Survey:** You will be asked to complete a survey that asks about your health, lifestyle and quality of life. This survey includes a 7-day sleep diary and a 3-day food diary. At the 6-week midpoint only, you will also be asked to complete a dietary food and activity questionnaire.
    b. **Clinical measurements**: We will ask you to attend a baseline clinic visit at the Rutgers Cancer Institute of New Jersey, where you will have your blood pressure, heart rate variability, height, weight, and waist/hip ratio measured. You will also complete a brief physical test.
    c. **Blood sample**: At the clinic, we will collect up to 3 tablespoons of your blood. Your blood sample will be used to examine biomarkers of health, cancer, aging, immune function, inflammation, as well as genetic and genomic markers. Studies of genetic and genomic involve the study of DNA and genes. Blood samples will be sent to the University of California Los Angeles (UCLA) for analysis and will be identified only by a study code number. The samples will not include any personal identifiers such as your name, address, etc.
    d. **You will be asked to submit a stool sample**. This sample will be used to examine the bacterial and microbial makeup of your digestive system.

2. **Be randomly assigned to 1 of 3 groups:**
    a. Usual Care: If you are assigned to usual care, you will simply continue with your usual care, OR
    b. Body Training: If you are assigned to body training, you will be asked to attend a 12-week program, led by a trained instructor, and participate in light intensity exercise classes for strength and flexibility, OR
    c. Body-Mind Training: If you are assigned to body-mind training, you will be asked to attend a 12-week program, led by a trained instructor, and participate in a series of exercises with low-intensity postures and deep breathing.

Body Training and Body-Mind Training groups will meet two times a week for one hour. You will be able to invite an adult companion (e.g., spouse, significant other, relative, or friend) to join the class with you. The group you are assigned to will be determined randomly. Randomization is a method used to ensure the research study is fair. It means that participants are assigned by chance to different groups. You will not be eligible to participate if you are not willing to be randomly assigned to one of these three groups.

<u>Participants will be asked to do the following</u>:

a. Wear a heart monitor during class and complete a short survey after class on a regular basis (Body Training and Body-Mind Training).

b. Perform home-practice sessions some of the days that there is not class (Body Training and Body-Mind Training) and complete home-practice logs to return weekly during health classes (Body Training and Body-Mind Training) or over the phone (Usual Care)
c. Complete a physical activity log and then turn in or report to staff by telephone weekly for 13 weeks (all groups).
d. You will be asked to wear a pedometer daily and to record your steps for 13 weeks. You will be able to keep the pedometer when the study is over (all groups).

3. **Complete follow-up assessments: You will be asked to complete follow-up surveys, clinical measurements, and submit blood and stool samples.**
    a. Surveys: You will be asked to complete follow-up surveys at the midpoint of the classes (6 weeks), and at 1-week, 3 months, and 12 months after the completion of classes. All groups will complete these surveys. If you are in the usual care group, the survey will be mailed to you.
    b. Clinical measurements/blood and stool sample: We will ask you to attend the Rutgers Cancer Institute of New Jersey or another Rutgers Clinic, where you will have your weight, waist/hip ratio, heart rate variability, blood pressure measured, complete a brief fitness test, and have up to 3 tablespoons of blood drawn. You will also submit a stool sample. Follow-up assessments will be at 1-week, 3 months, and 12 months after the completion of classes. All groups will complete all assessments.

What are the risks and/or discomforts I might experience if I take part in this study?
There are minimal risks to participating in this study. A potential but minimal risk in this study is the breach of participant confidentiality and privacy. Every effort will be made to protect the information you give us. The researchers are trained to protect your information and to use procedures that reduce the possibility of loss of privacy and/or confidentiality. It is possible that you may experience some psychological distress specific to coping with a stressful life event such as living with a previous cancer diagnosis. It is also possible that you will experience overall body or joint pain from the physical activity. The risks of injury during blood draw are minimal and include superficial bruises, discomfort and bruising at the site of the needle insertion, bleeding from the site of puncture, and uneasiness associated with needles. There may be risks that are unforeseeable.

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 interacting with other cancer survivors and receiving free instruction in a gentle form of body-mind exercise or body exercise that may improve your overall quality of life. You may also find satisfaction in contributing to important cancer research. However, it is possible that you may not receive any direct benefit from taking part in this study.

What are my alternatives if I do not want to take part in this study?
There are no alternative treatments available. 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 course of the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

Will I receive the results of the research?
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.

Will there be any cost to me to take part in this study?
You will not be charged, nor will your insurance company be charged, for any test or visit that is completed solely for the purpose of this study.

Will I be paid to take part in this study?
You will be compensated for your time. You will be given a $75 merchandise card for completing all requisite activities at five different time points during your participation in the study. These activities include completing surveys and providing blood and stool samples. As such, if you complete all activities at all time points you will receive $375 total for taking part in this study along the following schedule:

- $75.00 at your baseline clinic visit
- $75.00 at the intervention midpoint (no blood or stool samples at this time)
- $75.00 at the 1-week post-intervention clinic visit
- $75.00 at the 3-month post-intervention clinic visit
- $75.00 at the 12-month post-intervention clinic visit

If you are in the Usual Care group and complete all of the activities (surveys, blood draws, stool samples) or are in the Body Training group or in the Body Mind Training group and complete all of the activities (surveys, blood draws, stool samples) and attend a certain number of health classes, you will receive an additional $150.

Thus, the total potential compensation for your participation is $525. This is taxable income.

Study staff will track completion of surveys, blood draws, stool samples, and classes.

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.

Your name and other identifying information will be maintained in locked filing cabinets and secure computer files, available only to authorized members of the research team, for the duration of the study.

Your personal data will only be identified by a unique number (study ID). Research data will be stored separately from your name and other identifiable information. Any personal identifying information and any record linking that information to study ID numbers will be destroyed within 10 years of the end of the study.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institute of Health. The researchers will use this Certificate to legally refuse to disclose any information, documents or biospecimens that may identify you from disclosure, including a court order. This means that research collected about you for this study will not be released to anyone who is not connected with this study unless you request or consent to its release, a law requires its release, it is used for other scientific research, as allowed by federal regulations protecting subjects, or it is requested by the U.S. federal agency sponsoring the research that is needed for auditing or program evaluation.

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 or biospecimens collected for this research after the study is over?
After information that could identify you has been removed, de-identified information and biospeciments collected for this research may be used by or distributed to investigators for other research 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 the use of data already collected about you, but you must do this in writing to Dr. Anita Kinney.

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If you decide to withdraw from the study for any reason, you may be asked to return for at least one additional visit for safety reasons.

The investigators have the right to end your participation in this study if they determine that you no longer qualify to take part, if you do not follow procedures, or if it is in your best interest or the study's best interest to stop your participation.

Who can I call if I have questions?
If you have questions, concerns or complaints about the research, wish more information or if you feel you may have suffered a research related injury, you can contact the Principal Investigator: Dr. Anita Kinney, Cancer Institute of New Jersey, New Brunswick, NJ: 732-235-8545.
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 Office at (973) 972-3608 or (732) 235-9806 or (732) 235-2866 or email us at IRBOffice@research.rutgers.edu, or write us at 335 George Street, Liberty Plaza Suite 3200, New Brunswick, NJ, 08901.

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

The next few paragraphs tell you about how investigators want to use and share identifiable health information from your medical record in this research. Your information will only be used as described here or as allowed or required by law. If you sign this consent form, you agree to let the investigators use your identifiable health information in the research and share it with others as described below. Ask questions if there is something you do not understand.

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 investigators answer the questions that are being asked in the research.

What information about me will be used?
Your health information related to this study may be used or disclosed in connection with this research study, including but not limited to:

- Health information related to this study
- Biospecimens (blood and stool samples)
- Physical assessments
- Clinical Assessments
- Surveys
- Medications

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:

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

- Rutgers University investigators and staff involved in the study;
- UCLA investigators and staff involved in the study, including Co-Principal Investigator Dr. Michael Irwin, will have access to de-identified participant data.
- 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
- Rutgers University Data Safety Monitoring Board (DSMB) of the Rutgers Office of Research Regulatory Affairs.
- Members of regulatory authorities that may be required by law to look at this information.

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.

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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 study. (Saying no does not stop you from getting medical care or other benefits 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 research, you must write to the researcher and tell him or her of your decision:

Dr. Anita Kinney
Cancer Institute of New Jersey
195 New Albany Street
New Brunswick, NJ 08901

How long will my permission last?

AGREEMENT TO PARTICIPATE

1. Subject consent:

I have read this entire consent 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 and this study have been answered. I agree to take part in this study.

Subject Name:_____

Subject Signature:_____ Date:_____

2. Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed all the important details about the study including all of the information contained in this consent form.

Investigator/Person Obtaining Consent (printed name):_____

Signature:_____ Date: _____

Your permission for the use and sharing of your health information will not expire unless you withdraw it.