Participant Informed Consent for Clinical Research

Study title for participants: Researching the Effect of Exercise on Cancer

Official study title for internet search on http://www.ClinicalTrials.gov:
Phase 1a/b Trial of Exercise as Interception Therapy for Primary High-Risk Cancer

Subtitle: Phase 1a

Lead Researcher: Lee Jones, PhD (646-888-8103)

Overview and Key Information

Why is this study being done?

We are asking you to take part in a clinical research study. We do research studies to try to answer questions about how to prevent, diagnose, and treat diseases like cancer.

We are asking you to take part in this research study because you were previously treated for colorectal or breast cancer. Researchers think that exercise may be able to prevent cancer from coming back by changing circulating levels of various factors in a person's body (as measured in blood). We are doing this study to explore how aerobic exercise (exercise that stimulates and strengthens the heart and lungs and improves the body's use of oxygen) may favorably change the circulating levels of these factors to prevent or slow the return of cancer.

During the study, we will try to find the highest level of exercise that is practical, is safe, and has positive effects on the body that may prevent or slow the return of cancer. Each level of exercise we test will be a certain number of minutes each week. Once we find the best level of exercise, we will test it further in a new group of participants. All participants in this study will have been previously treated for colorectal or breast cancer.

Taking part in this study is your choice.

You can choose to take part or not to take part in this study, and you can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

This document presents important information to help you make your choice. Please take time to read it carefully. Talk with your doctor, family, or friends about the risks and benefits of taking part in this study. It's important that you have as much information as you need, and that all your questions are answered.

What is the usual approach to my condition?

People who are not in a research study usually follow up with their doctor to monitor their cancer. Their doctor may recommend ways to exercise.

What are my other choices if I decide not to take part in this study?

- You may choose to have the usual approach described above
- You may choose to take part in a different research study, if one is available

What will happen if I decide to take part in this study?

If you decide to take part in this study, you will participate in walking sessions 3-6 times a week for a total of 90-375 minutes each week. You will participate in these walking sessions for up to 18 months. The walking sessions will be on a treadmill we send to your home.

You will complete the exercise sessions at home, using our supervised home-based training program, and these sessions will be in a "virtual exercise space", allowing you to interact with the exercise physiologist and likely other participants who are also completing a supervised home-based training program for a research study. To do this, your home must have Wi-Fi access and space for a treadmill. The study team will provide you with all the necessary exercise equipment and monitoring devices.

You will have an End-of-Treatment visit within 3 weeks of your last walking session. We will check on your health at this visit. After the End-of-Treatment visit, we will continue to follow your health by reviewing your medical records following your routine visits. This long-term follow-up will continue until the study ends. (We think the study will last about 7 years.)

What are the risks and benefits of taking part in this study?

There are both risks and benefits to taking part in this study. It is important to think carefully about these as you make your decision.

Risks

We want to make sure that you know about a few key risks right now. We will also give you more information in the *What risks can I expect from taking part in this study?* section of this consent form.

If you choose to take part in this study, there is a risk that you could have side effects from the study approach.

Some of the most common side effects of aerobic exercise that the study doctors know about are:

- Feeling tired (fatigue)
- Muscle or joint pain

There may be some risks that the study doctors do not yet know about.

Benefits

Exercise may prevent or slow the growth of tumors, but we do not know whether this will happen in people with your condition. This study may help the study doctors learn things that could help other people in the future.

If I decide to take part in this study, can I stop later?

Yes, you can decide to stop participating in the study at any time.

The study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

If you decide to stop, let the study doctor know as soon as possible. It's important that you stop safely.

If you stop, you can decide whether to let the study doctor or a member of the study team continue to contact you to ask questions about your health. We will not be able to withdraw information about you that has been used or shared with others before you informed us of your decision to stop.

Are there other reasons why I might stop being in the study?

Yes. The study doctor may take you off the study if:

- Your health changes, and the study is no longer in your best interest
- New information becomes available, and the study is no longer in your best interest
- You do not follow the study rules
- The study is stopped by the National Cancer Institute (NCI), Institutional Review Board (IRB), Food and Drug Administration (FDA), or the study sponsor, MSK. The study sponsor is the organization that oversees the study.

It is important that you understand the information in this informed consent document before you make a decision about participating in this clinical trial. Please read, or have someone read to you, the rest of this document. If there is anything that you don't understand, ask the study doctor or nurse for more information.

What is the purpose of this study?

The purpose of this study is to find the highest level of aerobic exercise that is practical, is safe, and has positive effects on the body that may prevent or slow the return of cancer. All participants in this study will have been previously treated for colorectal or breast cancer. Once we find the best level of exercise, we will test it further in a new group of participants.

This study will also look at the way the body responds to exercise and whether participants' cancer comes back.

Researchers have found that measuring certain factors in the blood may help with predicting the risk of cancer returning. Researchers have been exploring the way exercise can change these factors and serve as an anticancer therapy. However, researchers have not yet found the level(s) of exercise that will be the most helpful for patients. This study will provide useful information about how different levels of exercise can affect these factors and possibly prevent or slow the return of cancer.

About 70 people will take part in this study at Memorial Sloan Kettering Cancer Center (MSK).

What are the study groups?

This study has two parts: dose escalation and dose expansion. You are being invited to participate in the dose escalation.

During dose escalation, different groups of study participants will get increasing levels of exercise. Each level of exercise will be a certain number of minutes each week. The first few participants will exercise for 90 minutes each week. If we find that the exercise level is safe and practical, the next group of participants will exercise for a higher number of minutes. The study doctor will watch each group carefully as the levels increase. The exercise level will increase for each new group of study participants until we find a level that is unacceptable (for example, because it is not safe or it is not practical). When this level is found, the dose escalation part of the study will be stopped. The highest level we may test

will be 375 minutes each week. Your study doctor will tell you your exercise level (i.e., 90, 150, 225, 300, or 375 mins per week). Which level you are assigned to will depend on when you enter the study.

During dose expansion, the best level of exercise that was found during dose escalation will be tested in a new group of study participants. This plan will help us learn more about how different levels of exercise can affect circulating blood factors and possibly prevent or slow the return of cancer.

What extra tests and procedures will I have if I take part in this study?

Before you begin the main part of the study:

The study doctor will review your medical records and the results of your exams, tests, and procedures to see if it is safe for you to take part in the study. This first part of the study is called screening. Most of the screening exams, tests, and procedures are part of the usual care that you would have if you were not in a study.

The tests and procedures that will be done only for research purposes, or that may be done more often because you are participating in this study, are listed below.

- Measure your pre-study general level of exercise during a normal week. You will receive a Withings smart watch (Steel HR) and an electronic tablet device to record your current general physical activity and exercise for 7 days. The watch (also called an activity tracker) connects to an app on the tablet so the app can record the information (data). This data can be sent to the study doctor through the app on the tablet. While you wear the watch, it will record:
    - Your general physical activity, using a step count based on your motion. The watch automatically detects the time and distance of walking and other exercises and movements.
    - Your sleep patterns, including how long it takes you to fall asleep, how long you sleep, sleep cycles, and sleep interruptions.
    - Your heart rate, in beats per minute
- If you do not have a recent electrocardiogram (ECG) within the last ~6 months from either MSK or outside, you may be asked to complete a remote electrocardiogram prior to starting the study to ensure safe participation. A handheld device will be used to complete the ECG from your home.
- Submaximal exercise tolerance test: You will walk on the treadmill at gradually increasing speeds and/or steepness (incline) until your heart rate reaches 80% of your maximum heart rate (the greatest number of beats made by your heart in 1 minute of effort). Your maximum heart rate will depend on your age. The test will be stopped before you become too tired. If you have any uncomfortable symptoms during this test, alert the exercise physiologist.
- A set of questionnaires that ask about your current levels of exercise, energy, and your overall well-being. It will take about 20 minutes to complete these questionnaires. The questionnaires may be completed on paper or on the study tablet.
- A collection of blood samples for research tests (about 3 ½ tablespoons). For this blood draw, you should not eat or drink anything except water (tea and black coffee are also permitted) for 8 hours before your blood is drawn. A trained medical technician may come to your home to collect the following samples:
    - About 2 tablespoons of blood will be collected for immune phenotypes testing to study your immune system.
    - About 1 ½ tablespoons of blood will be collected for cell-free DNA (cfDNA) testing to measure DNA that is not from a tumor.

- An optional stool sample to study the types of bacteria and DNA present in your intestines. A member of the study team will provide you with the materials and instructions on how to collect a stool sample at home.

During the study:

Participants will receive a study kit that includes a heart rate monitor, blood pressure cuff, and scale. In addition, you will receive glucose sensors, glucose (sugar water) drinks, and monthly stool kits if you choose to participate in these optional assessments. You will also receive a treadmill, and Exercise Oncology staff will coordinate shipment of the treadmill and study kit to your home. MSK owns the treadmill, tablet, and study kit. You will use them while you are taking part in this study, and you will have to return them when your participation in the study ends.

Figure 1. A patient exercising via TeleEx

You will complete all the exercise sessions at home, according to an individualized program in which you will walk on the treadmill for 3-6 days every week for up to 18 months. Your study doctor will let you know how many minutes you will need to spend exercising each week, not including the warm-up and cool down. The intensity level of the exercise sessions is considered mild to vigorous (requiring a lot of energy). This range of intensity is safe and tolerable for the people who are participating in this study.

For safety monitoring and to make communication easier between you and the study team during supervised home-based exercise sessions, the tablet device allows two-way communications ("virtual visits") with the study staff. These virtual visits will not be recorded. It is likely your exercise sessions will be scheduled to take place at the same time as those of other study participants. The tablet's meeting conference feature works as a "virtual exercise space" that allows the study staff to interact with several study participants at the same time. This helps replicate in-person group exercise visits/classes. There may be, on average, anywhere from one to three other participants in the virtual exercise space. Due to the multiple participants exercising in the same virtual visit, we cannot guarantee your confidentiality. It is possible that other participants will see you and hear information you share during the session(s).

Some of your exercise sessions may be unsupervised, and you will be asked to report information (such as your heart rate and the length of the session) to the study team at your next scheduled clinic visit. If your next scheduled visit is more than 72 hours after an unsupervised exercise session, a member of the study staff may contact you to get the information.

<u>Exams, Tests, and/or Procedures</u>

You will have tests and procedures during the main part of the study. The procedures that will be done only for research purposes, or that may be done more often because you are participating in this study, are listed below.

- Submaximal Exercise Tolerance Test

- Questionnaires
- You will need to wear the activity tracker (the Withings smart watch you received before the study) throughout your participation in the study. The tracker will continue to record your general physical activity, your sleep patterns, and your heart rate. In addition to the tracker, you may also receive a sleep tracking mat, if applicable. This information (data) can be sent to the study doctor using the mobile app installed on the tablet.
- Use the scale to measure your weight, fat mass, muscle mass, water weight, and bone mass every day. These measurements will be sent to the study doctor using the mobile app.
- Use the blood pressure monitor to measure your blood pressure every day. These measurements will be sent to the study doctor using the mobile app.
- Wear the optical heart rate monitor that captures your changing heart rate while you are exercising. These measurements will be sent to the study doctor using the mobile app.
- Collection of blood (about 3 ½ tablespoons) for immune phenotypes and cfDNA. A trained medical technician may come to your come to collect the blood samples.
- Your doctor may also collect a sample of your previously collected tumor tissue to submit for genetic research testing, including looking for mutations. Your study doctor will request a portion of your stored (archival) tissue samples that were collected during an earlier biopsy or surgical procedure from the hospital or medical center where the procedure was performed. If you do not have archival tissue, the test will not be performed. You will not receive the results of this test.
    - We will study your samples to improve our understanding of the way changes in genes can affect the risk of cancer and other diseases. Genes are the “blueprints” for our bodies. Sometimes genes may have changes that occur during your lifetime that can affect the way a gene works. These changes (mutations) may cause cells to grow rapidly and abnormally and become a cancer that you cannot pass on to your family members (somatic mutation). However, some people develop cancer because they were born with a mutation in a gene. People who develop cancer because of a genetic mutation usually inherit this genetic change from their mother or their father (germline mutation). Other family members (brothers, sisters, and children) may share this same mutation. Most people with cancer did not develop their disease because of an inherited mutation.
    - We will look for changes in your genes using a test called Whole Genome Sequencing or Whole Exome Sequencing (WGS/WES). Your data may be used to learn more about cancer and other diseases. Data from large numbers of people can help researchers learn how changes in the order (sequence) of genes might affect a disease or a person’s response to treatment, identify possible links between diseases, and provide new ideas for drug development and personalized therapies.
    - After your research test samples have been studied, if any part of them is left over, the material will be stored for an indefinite period of time for use in future research. Your sample(s), including your DNA, may be used or stored for as long as they are useful for research purposes.
    - You will not be given the results of any genetic research testing done on your samples. If you or your family are interested in learning more about inherited risk factors for cancer, ask your study doctor for a referral to MSK’s Clinical Genetics Service.
- You may agree to participate in the optional studies described below; more information is provided in the *Optional Studies* section at the end of this consent form.

- Glucose monitoring: If you participate, you will apply a small sensor on the back of your arm about seven times throughout the study. Each sensor can be worn for up to 14 days. The sensor will measure your blood sugar (the amount of glucose in your blood).
- Glucose tolerance test: If you participate, you will consume a glucose (sugar water) drink about seven times during this study (while wearing the glucose sensor) so we can see how your body reacts to glucose. Please note that, for safety purposes, this assessment does not apply to patients with diabetes.
- Stool sample: If you participate, you will be asked to provide stool samples about eleven times throughout the study to evaluate the types of bacteria and DNA present in your intestines. A member of the study team will provide you with the materials and instructions on how to collect a stool sample at home.
- Dietary assessment: If you participate, you will log 3 days' worth of meals seven times during the study using a dietary tracking app.

Data collected during this study will be stored in a mobile app that connects through Validic to your MyMSK (Patient Portal) account. Validic is a cloud-based technology platform securely connecting data from digital health apps and wearable health devices to MSK's portal system. A member of the study staff may sync this connection on your behalf. We are asking for your permission to collect information about you from the apps and/or devices mentioned in this form. These apps are designed and operated by third parties who make or support mobile fitness and nutrition devices. In order to participate in this research study, you must agree to use these apps and devices. Any information that you provide to or through these apps or devices is governed by the terms of use and/or privacy policies managed by third parties and/or the platforms, and not by MSK. However, once MSK is provided with your information from these apps or devices, MSK will then protect the confidentiality and security of that specific information as further described in this consent form. Your name will not be sent to or through these apps or devices. In addition, the third parties that operate these apps and devices will not have access to your name.

If members of the study team see anything in your exercise data that they think may affect your safety, your exercise session will be stopped, and the study team may determine when (or whether) the session can continue.

End-of-Treatment and follow-up visits:

You will have an End-of-Treatment visit within 3 weeks of your last walking session. At this visit, you will have exams, tests, and/or procedures. The procedures that will be done only for research purposes, or that may be done more often because you are participating in this study, are listed below:

- Submaximal Exercise Tolerance Test
- Questionnaires
- Collection of blood (about 3 ½ tablespoons) for cfDNA and immune phenotypes research testing
- Stool sample (optional)

After the End-of-Treatment visit, we will continue to follow your health by reviewing your medical records following your routine visits. This long-term follow-up will continue until the study ends.
(We think the study will last about 7 years.)

A Study Calendar that shows how often you will have these exams, tests, and procedures is provided at the end of this consent form. The calendar also includes exams, tests, and procedures that are part of your usual care.

Will I receive the results of my research tests?

You will not receive the results of any tests done for research purposes during this study.

What risks can I expect from taking part in this study?

If you choose to take part in this study, there is a risk that:

- You may lose time at work, school, or at home, and you may spend more time than usual in the hospital or doctor's office
- You may be asked sensitive or private questions that you do not usually discuss
- Someone unexpected may get access to your health information. MSK will protect your records so that your name and other identifying information will be kept private. The chance that your information will be given to someone other than the people described in the Research Authorization (below) is very small.
- There may be a risk in finding out new genetic information about yourself. New health information about inherited traits that might affect you or your family (blood relatives) could be found during a research study.

The intervention used in this study may affect how different parts of your body work, such as your liver, kidneys, heart, and blood. The study doctor will be testing your blood throughout the study. The results of these studies will not be added to your medical records, and you and/or your study doctor will not be informed of the test results.

There is also a risk that you could have side effects from the study intervention/study approach.

Important information about side effects:

- The study doctors do not know who will or will not have side effects.
- Some side effects may go away soon, some may last a long time, and some may never go away.
- Some side effects may be mild. Others may be very serious and may even result in death.

Important information about how you and the study doctor can make side effects less of a problem for you:

- If you notice or feel anything different, tell the study doctor. He or she can check to see if you are having a side effect.
- The study doctor may be able to treat some side effects.
- The study doctor may adjust the study intervention to try to reduce your side effects.

The tables below show the most common and the most serious side effects that researchers know about. There may be other side effects that the doctors do not yet know about. If important new side effects are found during this study, the study doctor will discuss them with you.

Possible side effects of aerobic exercise:

Common, some may be serious In 100 people receiving aerobic exercise, more than 20 and as many as 100 may have:
• Fatigue

Common, some may be serious In 100 people receiving aerobic exercise, more than 20 and as many as 100 may have:
• Muscle pain • Joint pain • Back pain • Shortness of breath (dyspnea) • Leg cramps • Sprain • Strain • Fractures

Rare, and serious In 100 people receiving aerobic exercise, 3 or fewer may have:
• Pain in the chest that may radiate to the jaw or arm, because not enough blood is reaching the heart • Low blood pressure, which may cause dizziness, lightheadedness, or fainting • Fast, hard, or irregular heartbeats • Sudden rise in blood pressure after a normal reading (rebound hypertension) • Fainting • Heart attack • Stroke

Let the study doctor know about any questions you may have about possible side effects. You can ask the study doctor questions about side effects at any time.

What are my responsibilities in this study?

If you choose to take part in this study, you will need to:

- Keep your study appointments
- Tell the study doctor about:
  - All medications and any supplements you are taking
  - Any side effects from these medications or supplements
  - Any doctor visits or hospital stays outside of this study
  - Whether you have been or are currently in another research study
  - Any changes in your health
- Let the study doctor know if you skipped or chose not to answer any of the questions in the questionnaire.
- Do not drink alcohol within 6 hours before an exercise session and do not eat a large meal or have caffeine or tobacco within 2 hours before an exercise session.

Is there a conflict of interest for this study?

This study is sponsored by Memorial Sloan Kettering Cancer Center (MSK) and funded by the National Institutes of Health (NIH). There are no known investigator and/or institutional conflicts of interest for this study.

What are the costs of taking part in this study?

You will not have to pay for the study devices or for tests and procedures done only for research purposes, as described above in *What extra tests and procedures will I have if I take part in this study?* These devices, tests and procedures include:

- Submaximal exercise tolerance tests throughout the study
- Collection and testing of blood samples for research purposes throughout the study
- Collection and testing of stool samples for research purposes throughout the study (optional)
- Treadmill
- Tablet
- Blood pressure cuff
- Activity tracker wristband
- Heart rate monitor
- Scale
- Glucose sensors (optional)
- Glucose drinks (optional)
- KardiaMobile ECG (if applicable)

You and/or your health plan/insurance company will have to pay for all the other costs of preventing your cancer while you are in this study. These charges include the costs of insurance co-pays and deductibles, as well as tests, procedures, or drugs that you get during the study to monitor your safety, and to prevent or manage any side effects.

Talk to your insurance provider and make sure that you understand what your insurance pays for and what it does not pay for if you take part in this clinical trial. Also find out if you need approval from your health plan before you can take part in this study.

The study doctor or nurse can help you find the right person to talk to if you are not sure which costs will be billed to you or your insurance provider.

Will I receive payment for taking part in this study?

You will not be paid for taking part in this study.

Your biospecimens (blood, stool, tissue) may be used in the development of new tests, drugs, or other products for sale. If they are, you will not receive any payment from the sale of these products.

What happens if I am injured or hurt because I took part in this study?

You will get medical treatment if you are injured as a result of taking part in this study.

If you think that you have been injured as a result of taking part in this research study, tell the study doctor or the person in charge of the study as soon as possible. The name and telephone number of the person in charge of this research are listed on the first page of this consent form.

We will offer you treatment for research injuries that happen as a result of your taking part in this study. You and/or your health plan will be charged for this treatment. Medical services will be offered at the usual charge. You will be responsible for any costs not covered by your health plan/insurance company.

If you think that your injury was a result of medical error, you keep all your legal rights to receive payment for treating the injury, even though you are in a study.

Who will see my medical information?

Your privacy is very important to us, and the researchers will make every effort to protect it. Trained staff at Memorial Hospital may review your records, if necessary.

Access to your protected health information will be limited to those listed in the Research Authorization form, which is a part of the informed consent process.

Your information may be given out, if required by law. For example, some states require doctors to make a report to the state health board if they find that a participant in a research study has a contagious disease like tuberculosis. However, the researchers will do their best to make sure that any information about you that may be released will not identify you.

In the future, your information (data) and biospecimens may be de-identified, which means that your data and/or biospecimens will be assigned a unique code, and the list that links the code to your name will be stored separately from your biospecimens and data. Your de-identified information and biospecimens may be used for research that has not been described in this consent form, and they may be shared with another investigator for future research. You will not be asked if you agree to take part in future research studies.

If your information from this study is used in any reports or publications, your name and anything else that could identify you will not be used. It is possible that your de-identified information from this study will be shared with other researchers outside of MSK and may be stored in public databases related to research. All requests for data sharing will be reviewed by the study sponsor, and if individual results are included in the data, they will not contain any identifiable information about you, such as your name, address, telephone number, or social security number. Your privacy is very important to us, and we use many safety procedures to protect your privacy. However, we cannot guarantee that no one will ever be able to use your information to identify you.

The study doctors have a Certificate of Confidentiality from the National Institutes of Health for this study. This gives MSK an additional way to protect sensitive information that identifies you in your records if it is requested as part of a legal proceeding. However, MSK may still be required to share some of your medical information if required by law.

A Federal law, the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you, or when setting the terms of your employment.

Be aware that this Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, long-term care insurance, or if you are a member of the military, or receive your health care through TRICARE, the Federal Employees Health Benefits Program, the Veterans Health Administration, or the Indian Health Service.

Where can I get more information?

You may visit the NCI web site at http://cancer.gov/ for more information about research studies, or for general information about cancer. You may also call the NCI Cancer Information Service to get the same information at 1-800-4-CANCER (1-800-422-6237).

A description of this clinical trial will be available on 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.

You can talk to the study doctor about any questions or concerns that you may have about this study, or to report side effects or injuries. You may also contact the lead researcher listed on the first page of this consent.

For questions about your rights while you are participating in this study, call the MSK Institutional Review Board (IRB) at 212-639-7592. If you have concerns, complaints, or input on research, or if you would like more information about the informed consent process, please contact the MSK Patient Representative Department at 212-639-7202.

Optional Studies:

This part of the consent form describes optional studies that you can choose to take part in. You will not get health benefits from any of these studies. The doctors leading this research hope that the results of these studies will help other people with cancer in the future.

The results of these studies will not be added to your medical records, and you and/or your study doctor will not be informed of the test results.

You will not be billed for these optional studies. You can still take part in the main study even if you do not participate in some or all of the optional studies. If you sign up for but cannot complete any of the optional studies for any reason, you can still take part in the main study.

Optional glucose monitoring:

If you choose to take part in this optional glucose monitoring study, you will wear a small sensor on the back of your arm that continuously measures blood sugar levels (the amount of glucose in your blood). You will be given more than one sensor. Researchers will use the information from this sensor for future research related to the impact of exercise on glucose levels.

You will apply a new sensor at Weeks 1, 12, 24, 36, 48, 60, and at follow-up. You will be instructed to wear the sensor for 14 days after each application.

The possible risks of the glucose monitoring sensor include a skin reaction to the sticky substance (adhesive) that keeps the sensor attached to the skin.

The results from the glucose monitoring will be used only for research, and not to guide your medical care.

Please check Yes or No. Your medical care will not be affected, no matter what you decide to do.

I agree to participate in the optional glucose monitoring:

☐ Yes ☐ No

Optional glucose tolerance test:
If you choose to take part in this optional glucose tolerance test, you will consume a 50-gram (1/3 cup) glucose (sugar water) drink. This test is used to see how your body reacts to glucose.

You must not eat any food for 8 hours before taking the tolerance test and not eat or drink water for 1 hour after the test. This test will be done at Weeks 1, 12, 24, 36, 48, 60 and at follow-up.

The possible risks of the glucose drink include nausea, vomiting, diarrhea, or fainting.

The results from the test will be used only for research, and not to guide your medical care.

Please check Yes or No. Your medical care will not be affected, no matter what you decide to do.

I agree to participate in the optional glucose tolerance test:

☐ Yes ☐ No ☐ N/A

Note: Patients with diabetes may not participate in this assessment.

Optional collection of stool samples for research testing:
If you choose to take part in this optional study, you will be asked to collect a monthly stool sample for the first 6 months on study, then every 3 months thereafter until the end of study. Researchers will use the information from tests on your samples to examine how your body responds to aerobic exercise.

The results from the test will be used only for research, and not to guide your medical care.

Please check Yes or No. Your medical care will not be affected, no matter what you decide to do.

I agree to have the optional stool samples collected:

☐ Yes ☐ No

Optional dietary assessment:
If you choose to take part in this optional dietary assessment, you will log 3 days' worth of meals at Weeks 1, 12, 24, 36, 48, 60 and at follow-up. You will use a dietary tracking app called Bitesnap that will be installed on the tablet provided by MSK. Bitesnap takes photos to identify foods you are consuming and collect information about your calorie and nutrient intake.

You may also choose to log meals throughout the study.

Please check Yes or No. Your medical care will not be affected, no matter what you decide to do.

I agree to participate in optional dietary assessment.

☐ Yes ☐ No

This is the end of the section about Optional Studies.

Research Authorization for the Use and Disclosure of Protected Health Information (PHI)

Researching the Effect of Exercise on Cancer

Federal law requires Memorial Sloan Kettering Cancer Center (MSK) to protect the privacy of information that identifies you and relates to your past, present, and future medical conditions (protected health information; PHI). We are committed to protecting the privacy of your information.

If you enroll in this research study, your protected health information will be used and shared with others, as explained below. MSK must obtain your permission before using or sharing your protected health information for research purposes. This form helps to make sure that you are informed of the ways in which your information will be used or shared in the future.

Carefully read the information below before you sign this form. By signing this form, you agree to the use and disclosure of your information for this research study.

1. What protected health information about me will be used or shared with others during this research?

- Your medical records
- Your research records, including new health information created from study-related tests, procedures, visits, and/or questionnaires
- Any health information or clinical data associated with your biospecimens, if the information or data could be reasonably used to identify you. This information or data will be shared only if you have agreed to it by signing this informed consent document.
- HIV-related information, including any information indicating that you have had an HIV-related test; or that you have HIV infection, HIV-related illness, or AIDS; or any information that could indicate that you may have been exposed to HIV. (New York State requires us to obtain your consent to use or share this information.)

2. Who will use or share my protected health information?

MSK will use and share your protected health information. People and offices that deal with research oversight, quality assurance, and/or billing will be able to use and share your protected health information, including:

- The study's Principal Investigator and Co-Principal Investigator: Lee Jones, PhD and Luis Diaz, MD
- Your research team at MSK, including the participating investigators, research staff, research nurses, fellows/residents, and clerical support staff
- Any healthcare personnel who provide services to you in connection with this study
- Members and staff of MSK's Institutional Review Board (IRB) and Privacy Board (PB)
- Staff of MSK's Clinical Research Administration, which oversees clinical studies, and Clinical Research Information Technology Group, which manages research databases
- Members of MSK's Data Safety Monitoring Board/Committee and the Quality Assurance Committee

3. With whom outside of MSK may my protected health information be shared?

Although all reasonable efforts will be made to maintain the confidentiality of your protected health information, it may be shared with and used by the following:

- MSK's research collaborators, business partners, subcontractors and agent(s), in the United States or in other countries, working to conduct the study, to monitor the study, or to analyze the study information for this study or for other research about the study intervention.
- Other research doctors and medical centers participating in this research.
- Federal and state agencies, and other domestic or foreign government bodies, if required by law and/or necessary for oversight purposes, including:
    - Office for Human Research Protections (OHRP) of the US Department of Health and Human Services (HHS)
    - US Food and Drug Administration (FDA) and other regulatory agencies responsible for oversight of research
    - National Cancer Institute (NCI)/National Institutes of Health (NIH)
- Other qualified researchers, approved by MSK, who may receive individual research results that do not identify you.

Some of the organizations that may receive your protected health information may not have to satisfy the privacy rules and requirements; they may share your information with others without your permission.

4. Why will my protected health information be used by or shared by MSK or others?

The main reasons for the use or sharing of your information include the following:

- To conduct the study, to monitor your health status, to measure the effects of the drug(s)/device(s)/procedure(s) being studied, and to determine the research results
- To ensure that the research meets legal and institutional requirements
- To develop new tests, procedures, and commercial products
- To enhance research databases, so that scientists can design better research studies to develop new therapies for patients and to gain a better understanding of disease
- To assist with MSK medical treatment, billing, or healthcare operations. For example, medical information produced by this research study will become part of your hospital medical record.

5. For how long will my protected health information be used or shared with others?

There is no set date at which your protected health information that is being used or shared for this research study will be destroyed or no longer used. The information used and created during the study may be analyzed for many years, and it is not possible to know when this analysis will be completed.

6. Statement of privacy rights:

- It is your right to refuse to sign this authorization form. If you do not sign this form, you will not be able to participate in this research study. However, if you do not sign, it will not affect your ongoing medical treatment or healthcare coverage.

- You have the right to withdraw your permission for MSK to use or share your protected health information. Please note that we will not be able to withdraw all the information about you that already has been used or shared with others to carry out research-related activities such as oversight, or information that is needed to ensure the quality of the study. To withdraw your permission, write to the study doctor listed on the first page of this consent form at: Memorial Sloan Kettering Cancer Center, 1275 York Avenue, New York, NY 10065. If you withdraw permission for us to use or share your protected health information, you will not be able to continue to participate in this research study.

- You have the right to request access to your protected health information that is being used or shared during this research and that is related to the research or to payment for the research. However, you may access this information only after the study is completed. You may have access to the parts of your medical record that are unrelated to this study at any time. To request this information, please contact the study doctor whose name and telephone number are listed on the first page of this consent form. You may also ask the study doctor to correct any study-related information about you that is wrong.

Notice concerning HIV-related information

Individuals/organizations are prohibited from sharing any HIV-related information about you without your approval, unless they are permitted to do so under federal or state law. You have a right to request the list of people who may receive or use your HIV-related information without your authorization.

If you experience discrimination because of the release or disclosure of your HIV-related information, you may contact the New York State Division of Human Rights at 888-392-3644 or the New York City Commission on Human Rights at 212-306-7500. These agencies are responsible for protecting your rights.

Participant Informed Consent/Research Authorization for Clinical Research

Statement of professional obtaining consent

I have fully explained this clinical research study to the participant. In my judgment, and in that of the participant, sufficient information, including risks and benefits, was provided for the participant to make an informed decision.

Consenting professional must personally sign and date		
Consenting professional's signature		**Date:**
Consenting professional's name (Print)		

Participant's statement

I have read this form that describes the clinical research study. I have also talked it over to my satisfaction with the consenting professional. By signing below, I agree to the following: (1) to voluntarily participate in this clinical research study; (2) to authorize the use and disclosure of my protected health information (data about myself); and (3) to state that I have received a signed and dated copy of this consent form.

Participant must personally sign and date		
Participant signature		**Date:**
Participant name (Print)		

Witness signature (if required)

- ❑ Witness for non-English speaking participant: I declare that I am fluent in both English and in the participant's language, and I confirm that the consent discussion was appropriately interpreted for the participant.
- ❑ Other: I confirm that the consent discussion occurred, and that the participant agreed to participate in this study by signing this form, making his/her mark, or verbally agreeing.

Name of witness: _____

Signature of witness: _____ **Date:** _____
(The name of the witness must be documented in the EMR.)

Interpreter (if required)

Name of interpreter (if present): _____

ID number (if phone interpreter): _____
(The interpreter's name or ID number must be documented in the EMR.)

The participant must be provided with a **signed copy** of this form.

Memorial Sloan Kettering Cancer Center
IRB Number: 20-378 A(9)
Approval date: 07-Oct-2024

Study Calendar:

This calendar shows the exams, tests, and procedures that will be done as part of this research study, as well as the tests and procedures that are part of your usual care.

Exam/Test/Procedure:	Screening/ Baseline	Week 1	Weeks 4 & 8	Week 12	Weeks 16 & 20	Week 24	Weeks 36, 48, & 60	Post-Intervention Follow Up
Current exercise behavior	X							
ECG (if needed)	X							
Submaximal Exercise Test	X			X		X	X	X
Questionnaires	X			X		X	X	X
Research blood collection	X		X	X	X	X	X	X
Stool collection (Optional)	X		X	X	X	X	X	X
Dietary assessment (Optional)		X		X		X	X	X
Plasma glucose (Optional)		X		X		X	X	X
Oral glucose tolerance test (Optional)		X		X		X	X	X
Check your health at your routine visits						X		X
General physical activity	Continuous							
Sleep	Daily							
Body weight	Daily							
Heart rate	Continuous							
Resting blood pressure	Daily							