The Ohio State University Combined Consent to Participate in Research and HIPAA Research Authorization

Study Title: Maintaining Fitness: Exercise in Patients with Hematologic Malignancy

Principal Investigator: Ashley Rosko, MD

Sponsor: National Cancer Institute

This is a consent form for research participation. It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.

Your participation is voluntary. You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.

You may or may not benefit as a result of participating in this study. Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.

You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate. If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

1. Why is this study being done?

You are being asked to participate in this study because you have a blood cancer and your doctor has referred you to participate in physical therapy. This research is investigating your overall health while undergoing physical therapy and home-based exercise.

This study is being done to see whether physical therapy and home based exercise can improve fitness levels in patients with a blood cancer undergoing therapy. Unfortunately, many people become tired and weak during cancer treatment. Instead of maintaining exercise, some people exercise less. However, many studies show that exercise is helpful for people who have cancer.

Fitness is a way of measuring the quality of health you are in. This research will describe a patient's fitness before, during, and after treatment (whether that treatment be chemotherapy, a bone marrow transplant, or other). To assess fitness, you will be asked to fill out surveys, go through supervised activities, and allow us to study up to 2 tablespoons of your blood. By completing these things, we hope to be able to better understand your ability to tolerate both exercise and treatment.

2. How many people will take part in this study?

Approximately 100 people will join the study.

3. What will happen if I take part in this study?

All parts of this consent form will be explained to you in detail by the researcher. If you choose to take part in this study, you will first be asked to sign the consent form for this research study as well as a Health Insurance Portability and Accountability Act (HIPAA) research authorization form.

Your medical records will be reviewed for eligibility. You will also take a short physical function test to evaluate your strength and balance. If you meet the eligibility criteria needed to participate in the study, you will then be assigned a unique ID.

You will meet with a physical therapist within one month of enrolling; you will take part in a physical therapist directed exercise program. You will meet with the physical therapist a minimum of twice monthly for 4 months. You will also be asked to perform exercises at home, individualized for your strength and function as outlined by your physical therapist. These exercises are personalized for you and based on your physical strength and abilities. Some of the home-based exercises you will be asked to do may include stretching, balancing, walking and muscle strengthening exercises. Your physical therapist will go over the exercises with you and provide you with instructions on how to do them. We will ask you to track your progress with home-based exercise using a diary. You will keep a log at home recording how often you did exercise and if you had any falls at home.

You will have 3 study visits in total. These study visits will take place at your oncologist's office in the clinic. The first study visit is at enrollment, the second study visit is at the end of the physical therapist-directed exercise program and the third study visit is approximately 6 months from the date of your initial study visit or physical therapy appointment, whichever occurs first. At each study visit, the following things will take place:

1) You will be asked to complete a questionnaire that consists of questions focused on what you do on a daily basis and how you feel. Your overall health will be evaluated using surveys that you complete inquiring about your mental health, quality of life, fatigue, social support, activities at home, medications and medical conditions that affect your health. Questionnaires will be on an iPad or on paper. This questionnaire

can be completed at your oncologist's office in clinic, before or after your regularly scheduled oncology appointment, and should take about 30 minutes.

2) A member of our research team will go through specific tests with you that include some tests on how you think and walking tests –these tests can be accomplished at your oncologist's office in clinic, before or after your regularly scheduled oncology appointment, and should take about 10 minutes.
3) Clinical information will be transferred into an electronic database, where it will be stored safely, and all information that may identify you will be removed or coded for your protection.
4) You will be asked to donate a small amount of blood (up to 30mL, or two tablespoons). You may decline to give blood at any time. Your blood will be collected during your regularly scheduled appointment. A research lab, here, at The Ohio State University will use the blood to evaluate markers and DNA of your immune system.
5) You will also be asked about your opinion of this exercise program at the completion of the program.

Some patients, during the course of their cancer care, will undergo a bone marrow transplant. If your doctor recommends during the course of this investigation that you would benefit from a bone marrow transplant, we will have a physical therapy team assess you during your inpatient hospitalization. The inpatient physical therapy team will assess you for your physical therapy needs and progress during this hospitalization. We will also be monitoring you for any falls during this time.

4. How long will I be in the study?

Study participants will be involved in this study for approximately 6 months.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University. If you change your mind, your authorization must be revoked in writing. To remove yourself from the study, please write to:

Ashley Rosko, MD
320 W 10th Ave.
A344 Starling Loving Hall
Columbus, OH 43210-1267

6. What risks, side effects or discomforts can I expect from being in the study?

Exercise:

Possible risks of taking part in the study would include exercise –induced injury or fatigue or over-exertion. Participation in a physical therapy program also presents a risk for muscle injury or falls. In order to decrease these risks and join this study, your primary medical oncologist has given you medical clearance to take part in physical therapy. You will meet with an exercise specialist regularly during the exercise program to make sure that you are exercising in a safe way. If problems come up as you exercise, the exercise specialist will help to adjust the exercise in order to lessen the risk of injury.

During the research study, you will be provided with any new information that may affect your health or willingness to take part in the study. You may be asked to sign a new consent form that shows that you have been informed of new information relating to this research study.

Collection of Clinical Information:

The only risk associated with the use of your clinical information for research is the risk that your confidential health information will be disclosed. To help prevent disclosure, the database will be stored safely, with password protection, and your identity will be protected (names will be replaced by code numbers and the key to the code will be stored in a different secure location). No information will ever be released or published in a way that identifies a patient.

Blood Donation:

A blood test will be done as part of this research. The blood test may be collected during your oncology clinic visit. For a blood test, the insertion of the needle to draw blood is painful; however, this discomfort is brief. For most people, needle punctures to get blood samples do not cause any serious problems; however, they may cause bleeding, bruising, discomfort, infections, dizziness, or fainting.

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

All health insurance companies and group health plans must follow this federal law. This law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Under Ohio law, health insurance companies cannot ask about the results of a genetic test or use any information obtained from genetic testing to make decisions about providing coverage or benefits for health care services.

Questionnaires:

You will be asked to complete questionnaires as part of the study. Some of these questions may make some people uncomfortable. There is also a very small risk that one of the questionnaires that you will be asked to fill out may upset you. If this occurs, please tell the research staff that is helping you fill out the forms. He or she will be able to refer you to someone to talk with. You will also be told to contact your doctor.

7. What benefits can I expect from being in the study?

Participation in this study may lead to better understanding of the disease that affects you, but there may be no direct benefit to you by your participation in this research study. All people taking part in this study will receive a personalized exercise program. If this study is successful, we hope that participants will feel better during their cancer treatment. We also hope to be able to expand this research to larger groups of patients undergoing treatment for their cancer, to see if this helps people live longer after a cancer diagnosis.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

Declining participation in this research study or stopping participation will not affect the medical care that you receive.

9. What are the costs of taking part in this study?

There will be no additional costs to you or your insurance company if you choose to participate in this research study.

10. Will I be paid for taking part in this study?

Yes, you will be paid $25 travel reimbursement at each physical therapy visit (a maximum of twice monthly for 4 months). That is a total of $200 if you complete all 8 visits. Payment will be given in cash at the time of visit. By law, payments to subjects are considered taxable income.

11. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

12. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time. If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

13. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

The NIH issues Certificates of Confidentiality for all NIH-funded studies, including this study. This Certificate provides extra protection for you and your study information,

documents, or samples (blood, tissue, etc.). The Certificates are issued so that we cannot be required to disclose any identifiable information collected about you as a part of this study in a lawsuit or legal proceeding. This is a layer of protection over and above the already existing protections in place for you and your information, documents, or samples.

However, these protections do not apply in some situations. For example, we may have to release your information if a law requires us to do so, if the Alliance Clinical Trials Network and, or the National Cancer Institute that is funding this study requests the information, or if the FDA tells us to release this information.
Please talk to your study team, or contact the Office of Responsible Research Practices at 614-688-8641, if you have questions.

Please visit the NIH website at https://humansubjects.nih.gov/coc/faqs to learn more.

If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office records. Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search the website at any time.

The researchers will examine and/or compare your results along with the results of others who were in the study. The researchers may present the findings at scientific meetings, or may publish the findings in medical literature. If anything is presented or published, there will be no way to identify you as an individual. The researchers may give the information to other researchers working with them to do research; however, nothing that could identify you will be included in the information.

Your identity will remain confidential, and your records will be used by these authorized representatives only in connection with carrying out their obligations relating to the research study. They will not be used for any other purpose or disclosed to any third party except with your permission.

Your study records will be kept in locked cabinets behind locked doors. Any information on computers will be password protected. Only study researchers and staff members will have access to your study information.

14. HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

I. What information may be used and given to others?

- Past and present medical records;
- Research records;
- Records about phone calls made as part of this research;
- Records about your study visits;
- Information that includes personal identifiers, such as your name, or a number associated with you as an individual;
- Information gathered for this research about:
  Physical exams
  Laboratory, x-ray, and other test results
  Diaries and questionnaires
- Records about any study drug you received.

II. Who may use and give out information about you?

Researchers and study staff.

III. Who might get this information?

- Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information;
- If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic or physician's office record;
- The sponsor of this research - National Cancer Institute. "Sponsor" means any persons or companies that are:
  - working for or with the sponsor; or
  - owned by the sponsor.

IV. Your information <u>may</u> be given to:

- The Ohio State University units involved in managing and approving the research study including the Office of Research and the Office of Responsible Research Practices.

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

- To do the research;
- To study the results; and
- To make sure that the research was done right.

VI. When will my permission end?

There is no date at which your permission ends. Your information will be used indefinitely. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

VII. May I withdraw or revoke (cancel) my permission?

Yes. Your authorization will be good for the time period indicated above unless you change your mind and revoke it in writing. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the researchers. If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, 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.

VIII. 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 and receive research-related treatment. However, if you are being treated as a patient here, you will still be able to receive care.

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

There is a risk that your information will be given to others without your permission. Any information that is shared may no longer be protected by federal privacy rules.

X. May I review or copy my information?

Signing this authorization also means that you may not be able to see or copy your study-related information until the study is completed.

15. Who can answer my questions about the study?

For questions, concerns, or complaints about the study you may contact the **Principal Investigator of the study, Ashley Rosko at (614) 293-7807.**

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact **Ashley Rosko at (614) 293-7807.**

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this combined consent and HIPAA research authorization form**.**

Printed name of subject	**Signature of subject**
	AM/PM **Date and time**
Printed name of person authorized to consent for subject (when applicable)	**Signature of person authorized to consent for subject (when applicable)**
Relationship to the subject	**AM/PM** **Date and time**

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	AM/PM **Date and time**