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Department/ Section of Internal Medicine, Cardiovascular Medicine

IMPROVING EXERCISE CAPACITY WITH A TAILORED PHYSICAL ACTIVITY INTERVENTION IN LYMPHOMA AND BREAST CANCER PATIENTS UNDERGOING TREATMENT

Informed Consent Form to Participate in Research
Gregory Hundley, MD, Principal Investigator

SUMMARY

You are invited to participate in a research study for patients with Non-Hodgkin and Hodgkin lymphoma or breast cancer patients. The purpose of this research is to test whether participating in either a physical activity intervention or a series of educational classes will help to preserve exercise capability, heart function, brain-based activities (like memory), and your quality of life.

Your participation in this study will last about 7 months. Participation in this study will involve completing unsupervised and supervised exercise sessions or attending online educational sessions. You will also complete a series of tests at baseline, 3-months, and 6-months.

All studies involve some risks. Risks to this study that you should be aware of include the small chance that exercise testing could lead to symptoms of heart disease or injury, injury due to a loss of balance or a fall in home-based physical activities and testing, and discomfort associated with enclosed spaced during MRI scans. You may or may not benefit from participation in this study.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study please contact the Principal Investigator at [redacted].

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Wake Forest University Health Sciences Research Subject Advocate at [redacted].

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INTRODUCTION

You are invited to participate in a research study for patients with Non-Hodgkin and Hodgkin lymphoma patients or breast cancer (stage I-III. The purpose of this research is to test whether participating in either a physical activity intervention or a series of educational classes will help to preserve exercise capability, heart function, brain-based activities (like memory), and your quality of life.

Your participation is voluntary. You do not have to be a part of this study if you do not want to. Please take your time in making your decision if you would like to join. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research is to test whether participating in either a physical activity intervention or a series of educational classes will help to preserve exercise capability, heart function, brain-based activities (like memory), and your quality of life.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Up to 110 people at two research sites will take part in this study, including approximately 55 people at this research site. These subjects will be Non-Hodgkin and Hodgkin lymphoma or breast cancer patients that expect to receive toxic cancer treatment.

WHAT IS INVOLVED IN THE STUDY?

If you agree to participate in the study, you will be met by a study team member who will verify your medical history, current medications, identify any illness or injury that would prevent MRI or exercise testing, and answer any questions you may have about the study.

You will then be randomized into one of two pathways. Randomization is the process in which you would be put into a group by chance. In this study, you have a 1:1 chance to be in the second pathway versus the first pathway. In the first pathway, you will participate in organized health workshops. These workshops are intended to provide information on topics such as proper nutrition, management of stress, sleep practices, and emphasis on a healthy lifestyle that may help you as you continue through your cancer treatment. This pathway will also test whether stretching may help you as you proceed through cancer treatment. In the other (second) pathway of the study, you will participate in some unsupervised and potentially some supervised moderate activity sessions each week throughout your cancer treatment. The workshops and unsupervised or supervised activity sessions are designed to take place either remotely or in-person, depending on the availability of facilities at the time the visits are scheduled. The supervised sessions will be offered intermittently, as testing centers can accommodate and as appropriate for research

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participants.
You may not be able to participate in the in-person aspects of this study if you have been recently affected by COVID-19 or if you have been in close contact with a person affected by COVID-19. Prior to each visit, you may be asked to undergo screening questions and tests for COVID-19 as per standard protocol at the testing facility, which may include answering questions about your health, measuring your temperature, or having a nasopharyngeal test (swab of your nasal area) performed to detect the presence of SARS-CoV2 virus. During your visit you may be asked to wear a mask depending on the requirements in place at the testing facility.

Whether you participate in the first or second pathway, you will also undergo a series of:

1. Tests including MRI scans, blood draws, strength, walking, and a cardiopulmonary exercise test performed in an MRI scanning facility. This will depend on the ability of the testing facility to accommodate in-person testing at the time of your scheduled visit. If in-person testing is restricted, some or all of these tests will not be performed.
2. Questions that ask you about your diet
3. Questions that ask you about your quality of life, and
4. Questions that test your cognitive or brain function for things like memory, recognition of numbers, etc.

MRI and Exercise Testing:

I have worked with grinding metals (welding materials): Yes ☐ No ☐

If so, you will be required to complete a scan of your eyes prior to the MRI and exercise testing.

In-person testing:

For the cardiopulmonary exercise test in the MRI facility, please wear loose clothes and comfortable walking shoes.

You will first lie down in the MRI scanner, in which images of your heart will be taken. For the MRI portion of the study, you will need to go to the MRI scanning facility. After arrival at the MRI suite, you will be asked to fill out an MRI Participant Screening Form, which the MRI technologist will review with you prior to your MRI examination.

- A locker with a lock will be assigned to you where you can place your belongings while you are in the scanner.
- Afterwards you will be escorted to the MRI suite where you will be positioned on the MRI table.
- You will then be advanced into the MRI scanner for scanning. You will hear the normal "knocking" sound of the magnet during each scan and will be given a headset or earplugs to reduce the noise. Some people become anxious when advanced into the closed space of the scanner. If this happens to you, we will remove you from the scanner immediately.

Once we begin the scanning process, we ask that you remain as still as possible. On occasion,

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you may be asked to hold your breath for periods of time lasting 10-30 seconds. You will then be escorted to a treadmill outside of the MRI room. You will walk on a motor- driven treadmill with the amount of effort increasing gradually. The speed and grade of the treadmill will increase every two minutes and you will continue until symptoms such as fatigue, shortness of breath, or chest discomfort may appear, at which point the test will be terminated. We would like for you to exercise as long as possible. Staff present will remain in constant communication with you to determine when you feel that you are in your final 30 seconds of exercise. At this point, the staff will transfer you back to the MRI scanner.

During the performance of the test, a physician and other trained observer will monitor you and would stop the test if abnormal responses occur. Oxygen consumption (i.e., how much oxygen your body uses) will be measured through a mouthpiece during the test to measure your exercise capacity.

Certain changes may occur during these tests. These changes include abnormal blood pressure, fainting, disorders of heart beat (too rapid, too slow, or ineffective), and, in very rare instances, heart attack and death. The mouthpiece may cause slight mouth dryness but no other complication. Every effort will be made to minimize such changes through the preliminary examination and observations during testing. Emergency equipment and trained personnel will be available to deal with unusual situations that may arise.

At the completion of the exercise test, you will leave the treadmill and return to the MRI examining table within 1 minute after ceasing exercise to capture further images. This test will be performed during your first study visit and then, in identical fashion, at the 6 month study visit.

Strength and Walk Testing:

At each visit, you will complete a series of strength and walking tests. All of these tests should take about 15 minutes to complete. The test battery includes:

a. Grip strength test: Involves squeezing the handle of a device that will measure the amount of strength you can generate
b. Chair stand test: Involves measuring the amount of time it takes to stand from a seated position and how many times it can be completed in 30 seconds.
c. 6-minute walk test: Involves measuring the distance a participant can walk in 6 minutes

We can send copies of your test results to you and to your personal physician. Even if you do not wish to have any of your medical information sent to you and to your physician, you can still participate in this research study.

Do you request that we send important medical findings from your study tests/exams to you and to your personal physician?

[ ] Yes [ ] No _____Initials

ActivPAL & ActiGraph:

At the end of each testing visit, you will receive an ActivPAL activity monitor to validate your

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daily and weekly targets for physical activity. An ActivPAL is a small, thigh-worn device that continuously measures activity, sitting time or movement. You may also be asked to wear an additional activity monitor, the ActiGraph, which is a small, wrist-worn device that continuously measures activity.

Blood Draw:

During each of your research visits, you will have 2 tablespoons of blood withdrawn from either a vein in your arm or a currently placed central line port-a-cath. A portion of your blood from each visit will be used to collect information about your fatty acids and blood cell count.

After your blood is drawn, a portion of your blood sample will be used to detect markers of inflammation and evidence of heart injury and stored within the clinical research unit (CRU) or the Melendez laboratory at Atrium Health Wake Baptist Medical Center indefinitely. An additional portion of your blood will be saved from each visit for future testing This saved portion will be given only to researchers approved by Dr. Gregory Hundley. The total amount of blood withdrawn during your participation in this study will be approximately 2 ounces. In the future, research on your specimen may involve whole genome sequencing.

Dietary Interviews: At baseline, 3 months, and 6 months visits, the investigators will ask you some questions about your diet, particularly regarding what you ate during the 24 hours prior to the visit and two additional times over Zoom or telephone during the same week of the visit. We will also ask you some questions about your general appetite and pleasantness of your typical diet. Taken together, these procedures will last approximately 25 minutes.

Body Composition:
We may also measure your height and weight, and waist circumference.

Questionnaires:

Also at each visit, you will be asked to complete several questionnaires that will measure your fatigue, general health, social determinants of health, cognitive function (tasks that assess memory, ability to count, etc.) and physical activity. The questionnaires will take 15-40 minutes to complete. You will be given the option to complete these questionnaires electronically at your convenience prior to your research visits or if you will not be participating in in-person visits, using a link to a secure web application named REDCap.

PATHWAY 1 – HEALTHY LIVING INSTRUCTION (HLI):

Individuals in this group will log in to an online meeting space to participate in organized health workshops. Each session will last about 60 minutes. Session attendance will be required once a week for the first month, every other week for the next 3 months, and then once a month for the last two months. Make up sessions will be offered for those who must miss a group session in person, online, or over the telephone. We may contact you via telephone 1-2 times a month in addition to regularly scheduled sessions.

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Session Content: Introduction and Review past material (10 mins); Interactive Healthy Living Presentation (30 mins); Short instructor-led program of stretching exercises (10 mins); Wrap-Up, Questions and Promotion of next Workshop (10 mins).

The Healthy Living presentations will be interactive and will provide useful information on such topics as proper nutrition, management of stress, and sleep practices. Experts across a broad range of relevant topics will be brought in to give guest lectures over the course of the 6 months. Participants will be asked to complete homework assignments, review past topics, and engage in small group discussions as a means to increase active involvement in this study arm. The final component of the workshop, the stretching component, will be performed at each visit.

PATHWAY 2 –PHYSICAL ACTIVITY INTERVENTION (PAI):

Patient PAI will be performed either independently or at the Health and Exercise Science Clinical Research Center near the Reynolda Campus of Wake Forest University or other Cardiovascular Rehabilitation Facilities in your community with supervision of clinical exercise physiologist. Center-based Patient PAI sessions will be offered when facilities are available. Participants will have the ability to participate in two to four training sessions per week. Each Patient PAI session will consist of a slow (15min) aerobic warm-up; 20 minutes of strength training; 15 minutes of progressive intensity aerobic exercise (AE); followed by 10 minutes cool-down by stretching/toning with elastic bands similar to those recommended by the American Cancer Society.

The mode of activity for the center-based AE sessions will be over-ground walking and/or stationary cycling. This approach adheres to the principle of progressive intensity and is designed to increase exercise capacity outcomes (peak VO2 peak and 6min walk distance), yet also permit individual "tailoring" based on each participant's daily perceived level of fatigue and disease/treatment related symptoms. Each session is progressively modified with regard to the intensity and duration along with appropriate rest and recovery sessions.

Every two weeks there will be the possibility of introducing a single activity session which will be dedicated to short periods of high activity level separated in time by periods of low activity level. The advantage of these once every two weeks training sessions is that the duration of the AE session can be decreased and yet the physiological stimulus can increase to produce greater physiological adaptations.

Home based activities will be offered if you are unable to travel to the exercise center. The exercises will be constructed similarly to the center-based exercise and tailored to your access to equipment and symptoms. The study interventionist will work with you to create an exercise session and find creative ways to complete different types of exercises. Exercises could include, but not limited to, over ground walking, body weight exercises, or use of resistance bands.

In addition, participants will be encouraged to accumulate 150 minutes (~30 minutes day) of moderate-light intensity physical activity per week outside the program facility. This can be achieved through a variety of domestic and recreational activities performed at home. The daily and weekly targets for physical activity will be self-monitored by the participant and validated weekly by the intervention staff from the objective data obtained by a thigh-worn ActivPAL and

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a wrist-worn Fitbit activity monitors. An ActivPAL monitor is a small device that continuously measures activity, sitting time or movement.

To enhance safety, each subject will be instructed to participate at an individually prescribed level of exertion, report any symptoms or problems they might encounter during physical activity, and to rest as needed. The interventionist will take time to communicate with participants during the center-based AE sessions in order to determine whether physical activity prescriptions are appropriate, to ask how participants are feeling, and to answer questions regarding the physical activity prescription.

STORAGE OF BIOLOGICAL SPECIMENS

If you agree to participate in this study, some of the samples will be kept and may be used in future research to learn more about other diseases and inflammatory markers. The samples will be stored within the clinical research unit (CRU) or the Dr. Giselle Melendez Cardiovascular Research Laboratory at Atrium Health Wake Baptist Medical Center for future unspecified research. Samples may also be stored at Virginia Commonwealth University in Dr. Fadi Salloum's laboratory. Samples may be transported between labs. Samples will only be provided upon receival of an IRB approved protocol and are researchers approved by Dr. Greg Hundley. An Institutional Review Board (IRB) must also approve any future research study using your tissue sample. In the future, research on your specimen may involve whole genome sequencing.

The research that may be performed with your blood sample is not designed to help you specifically. There is no personal benefit to you from taking part in this aspect of the research study. The results of the research performed with your blood will not be given to you or your doctor. The results will not be put in your medical record. The research using your blood sample will not affect your care.

Your blood sample will be used only for research and will not be sold. The findings from this research may result in the future development of products that are of commercial value. There are no plans to share any of the profits with you which may occur as a result of the research.

Your blood sample will be stored with a unique identifier and will not include any identifiable information about you such as your name, address, telephone number, or social security number. The unique identifier will be a randomly assigned number and only the principal investigator will have access to the code that links the unique identifier to you.

As part of this research study, you will be asked to provide a biological specimen (i.e. blood, urine, saliva, etc.) to be stored and kept for future research. The future research may include studying your genetic information. At some point in the future, we may be required to share genetic data with federal repositories. The National Institutes of Health (NIH) and other central repositories have developed special data (information) banks that collect the results of genetic studies, especially when the research looks at all or large sections of individual's genetic code. This is often called whole genome sequencing. Genomic information relates to the structure and function of all of the genetic material in the body. These central banks will store your genetic information and give them to other qualified and approved researchers to do more studies. The data that we share with federal repositories will be coded in such a way that you would not be

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able to be identified. We will not share your name, birth date, or any other information that could directly identify you. The link to the code would be kept securely by the researcher. Even so, there is a possibility that when your genomic information is combined with other information available to researchers, either now or in the future, they may be able to identify a group you belong to (like an ethnic group or a disease population) or, less likely, you personally. NIH prohibits people from trying to identify individuals whose genomic information is in an NIH-designated repository.

We do not think that there will be further risks to your privacy and confidentiality by sharing your genetic information with these banks. However, we cannot predict how genetic information will be used in the future. The genetic data could be used to study a wide variety of diseases.

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 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 that we get from this research 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, or long-term care insurance, nor does it protect you against genetic discrimination by all employers.

How Long Will I Be in the Study?

Approximately a 7-month period.

You can stop participating at any time. If you decide to stop participating in the study, we encourage you to talk to the investigators or study staff first.

WHAT ARE THE RISKS OF THE STUDY?

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff. Risks and side effects related to the procedures we are studying include:

Risks of COVID-19 testing
A COVID-19 (coronavirus) nasopharyngeal test can be an uncomfortable procedure. This test typically involves the use of a nasal swab. Determining whether you have been exposed to and carry the COVID-19 virus is important for your own safety and that of other patients and study

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staff.

Risks of Exercise Testing or Exercise Interventions
A small chance exists that the exercise test could lead to symptoms of heart disease or injury. About 1 in every 10,000 patients with heart disease dies during an exercise test, and serious complications such as heart attack, prolonged chest pain or serious heart rhythm problems can happen in approximately 4 of every 10,000 participants.

During exercise intervention or testing, there is a chance you could lose your balance, trip, or fall. To minimize this risk, trained staff will ensure proper training technique to prevent injury and undue risk. As well, the exercise test could result in findings that might be helpful (for example, early detection of a particular condition) or troublesome (for example, causing you worry, involving additional and perhaps costly testing that may or may not benefit your health).

Home-based physical activities:
There are slight risks of participating in the home-based physical activity including injury due to a loss of balance or a fall, muscle discomfort or strain. However, the use of balance screening tests and the measurement of resting ECG and blood pressure are designed to limit these risks as much as possible and we do not expect the risks to outweigh those associated with participating in routine activities of daily living.

Risks of MRI Scans
MRI scans are not associated with any known side effects. Some subjects experience discomfort associated with enclosed spaces during MRI scanning. All standards of care used to monitor for any potential side effects that are used for clinical MRI facility today will be implemented and the exercise test will be carefully monitored by a cardiologist and exercise physiologist.

Risks of Blood Draws
You may experience discomfort, bruising and/or bleeding where the needle is inserted during the blood draw. Occasionally some people become dizzy, lightheaded or feel faint. Infection may occur on rare occasions. Frequent donation of blood can result in low iron in your blood (iron deficient anemia). You should not donate blood more than 2 times per week and no more than approximately one pint (about 500 ml) of blood in an eight week period.

Risks of dietary interviews:
Other than the inconvenience of answering questions, there are no known risks or discomforts related to the dietary recall.

Risks of Surveys and Questionnaires
In this study you will fill out questionnaires. These questionnaires will ask about how you are feeling. These feelings may become more intense when you fill out these questionnaires.

Risks of Providing Confidential Information
In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping

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research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

There also may be other side effects that we cannot predict. You should tell the research staff about all the medications, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects, interactions and other risks.

Reproductive Risks
Pregnant women are excluded from participation in this study. Women who might become pregnant should use a medically accepted form of birth control such as total abstinence, birth control pills, an IUD, diaphragm, progesterone injections or implants, or condoms plus a spermicide. Methods of birth control other than total abstinence are not 100% effective, and should a woman become pregnant there is a risk of injury to an unborn child.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct benefit to you. We hope the information learned from this study will benefit other people in the future. Results from this study could provide additional information about your cardiovascular health that could be accessed by your primary care physician to better manage your care. Occasionally, these new findings provoke anxiety until they are resolved. The study team will assist the participant in referrals so that any new findings will be taken care of immediately. We hope the information learned from this study will benefit other people in the future.

WHAT OTHER CHOICES ARE THERE?

Your alternative is not to participate, or you may want to ask local facilities if they have such a program for cancer patients.

WHAT ARE THE COSTS?

There are no costs to you for taking part in this study. All study costs, including any study medications and procedures related directly to the study, will be paid for by the study. Participants who are randomized into the "Participants Pathway 2" will be provided a Fitbit at no charge to use during their participation in the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

As part of this program we may ask you to wear a Fitbit device, which collects information about

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your heart rate and physical activity levels. For privacy purposes, we may provide you an anonymous Fitbit account, and will ask you to use this account throughout the study. Still, it may be possible for individuals, such as people who work for Fitbit or people in the general public, to be able to see information about your physical activity levels. You may reconsider participation in this research study if you are not comfortable with this.

TEXT MESSAGE COMMUNICATION. I give permission to Atrium Health, Wake Forest University Health Sciences, and their respective affiliated entities and representatives (including third-party agents if applicable) to contact me by text message at the number I provided to send information, reminders, and to communicate with me about the research study. I understand that I am responsible for the standard text message rate of my carrier. I also understand that text messaging is not a secure form of communication, and I accept the risk that individuals not involved in the research study may be able to access the text messages. I also understand that texting is not to be used for emergency situations.

☐ Yes, you can text me.

☐ No, you cannot text me.

EMAIL COMMUNICATION. By providing my email address, I give permission for Atrium Health, Wake Forest University Health Sciences, and their respective affiliated entities and representatives (including third-party agents if applicable) to send me information, reminders, and messages about the research study by email. I understand that these email messages may not be encrypted, and I understand and accept the risks that individuals not involved in the research study may be able to access unencrypted email messages. I also understand that email is not to be used for emergency situations.

☐ Yes, you can email me.

☐ No, you cannot email me.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United

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States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institutes of Health (NIH) which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of the results from the following research activities of this study: Exercise tests, MRI exams, blood draws, surveys and questionnaires.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document to a) allow important medical findings from your study tests/exams be sent to your personal physician and b) regarding information about your participation in the study being placed in your medical record, along with any routine medical test results that were obtained as part of this study.

WILL YOU BE PAID FOR PARTICIPATING?

Parking validation will be provided for all study-related visits. You may be reimbursed for accommodations needed for your study visits. Please discuss with the study coordinator. In addition, you will be compensated for each study visit you complete. You will receive $25.00 for completing the baseline visit, $35.00 for completing the 3-month visit, and $50.00 for completing the 6-month visit. This may be provided to you in the form of a gift card or prepaid debit card.

Total payments within one calendar year that exceed $100 will require the University to report these payments annually to the IRS and you. This may require you to claim the compensation you receive for participation in this study as taxable income. WFU is required by federal law to collect your social security number. Your social security number will be kept confidential and will only be used to process payment.

To receive payment, you must provide your social security number, name, and address so that we can comply with IRS (Internal Revenue Service) reporting requirements. When payments are reported to the IRS, we do not let them know what the payment is for, only that you have been paid. If you do not wish to provide this information you can still take part in this study, but you will not be paid.

WHO IS SPONSORING THIS STUDY?

This study is being co-sponsored by the Wake Forest University Health Sciences, Wake Forest Baptist Comprehensive Cancer Center, the National Institutes of Health (NIH) and the American Heart Association (AHA). Wake Forest Baptist Comprehensive Cancer Center is providing resources to help run the study. The NIH and AHA sponsors are providing money or other support to Wake Forest University Health Sciences to help conduct this study. The researchers do

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not, however, hold a direct financial interest in the sponsor or the product being studied.

Dr. William G. Hundley is paid by the American Heart Association (AHA), the entity which is the sponsoring a portion of this research, as an associate editor for the journal, Circulation, and a co-host for the podcast titled Circulation on the Run.

WHAT HAPPENS IF YOU EXPERIENCE AN INJURY OR ILLNESS AS A RESULT OF PARTICIPATING IN THIS STUDY?

Should you experience a physical injury or illness as a direct result of your participation in this study, Wake Forest University School of Medicine maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of such injuries or illnesses. To the extent research insurance coverage is available under this policy the reasonable costs of these necessary medical services will be paid, up to a maximum of $25,000. Wake Forest University Baptist Medical Center holds the insurance policy for this coverage. It provides a maximum of $25,000 coverage for each claim and is limited to a total of $250,000 for all claims in any one year. The Wake Forest University School of Medicine, and the North Carolina Baptist Hospitals, Incorporated do not assume responsibility to pay for these medical services or to provide any other compensation for such injury or illness. Additional information may be obtained from the Medical Center's Director of Risk and Insurance Management, at [redacted].

If you are injured, the insurer may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.

You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury you should call Gregory Hundley at [redacted].

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you and/or about your health or behaviors is considered Protected Health Information. The information we will collect for this research study may include the following**:** Name, date of birth, height, weight, medical record number, address, contact information, oncology and cardiac related health and treatment information, research generated data/information, serum hematocrit measures, MRI measures, and exercise capacity measures.

If this research study involves the diagnosis or treatment of a medical condition, the Protected Health Information collected from you during this study may be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist Atrium Health Wake Baptist Medical Center operations.

We will take steps to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected

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computer.

Your personal health information and information that identifies you ("your health information") may be given to other during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports, and to get approval for new products.

Some of the people, agencies, and businesses that may receive and use your health information are the study investigator and his/her staff, or others at Wake Forest University Health Sciences and Atrium Health who oversee research; Wake Forest University Health and Exercise Department; the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers, or analysis centers; the Institutional Review Boards; representatives of Wake Forest University Health Sciences and Atrium Health Facilities; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS), and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs, videotapes, audiotapes or other recorded media which are identify you unless we you're your written authorization.

Monitors, auditors, IRB or other regulatory agencies will be granted direct access to your medical record for verification of clinical trial procedures or data to the extent permitted by other applicable laws. These monitors, auditors, and other individuals are also required to maintain the confidentiality of your protected health information.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept an indeterminate period of time. This authorization does not expire and any research information entered into your medical record will be kept for as long as your medical record is kept by Atrium Health Wake Baptist Medical Center. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Gregory Hundley, MD, that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

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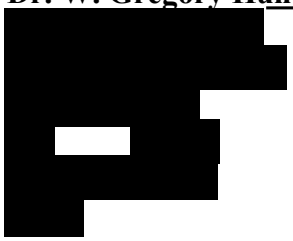

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

If you choose to participate in this study, your medical record at Atrium Health Wake Baptist Medical Center will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. Authorization to access this part of the medical record will only be available to people who have a need to know this information in order to perform their job-related duties. If you are not a patient at Atrium Health Wake Baptist Medical Center, a medical record will be created for you anyway to provide access to this important information to providers in case of an emergency.

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 this Web site at any time.

Laboratory test results and other medical reports created as a result of your participation in the research study may be entered into the computer systems of Atrium Health Wake Baptist Medical Center. These will be kept secure, with access to this information limited to individuals with proper authority, but who may not be directly involved with this research study.

An Atrium Health Wake Baptist Medical Center medical record will be created for all study participants seen on-site and if a medical record doesn't already exist. Information about your participation in the study will be placed in the Atrium Health Wake Baptist Medical Center medical record, along with any routine medical test results that were obtained at Atrium Health Wake Baptist Medical Center as part of this study.

What else do I need to know?

Participants who are randomized into the "Physical Activity Intervention (PAI) will be provided a Fitbit at no charge to use during their participation in the study. If you are in this group, you will also use the Trainerize application to complete your exercise intervention. If you have your own personal activity tracking device (Apple watch, Garmin or Fitbit) you will be asked to sync your device with the Trainerize application and will not be given an additional Fitbit. This device will collect physical activity training adherence data (e.g., steps walked per day). This information will help the study team better understand your adherence to the intervention protocol and or help to

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identify whether you are having any challenges with completing the exercise prescription that you may receive if you are randomized to the PAI group.

If you do not want to use the Fitbit and/or the Trainerize application, you should not agree to be in this study. If you do agree to be in this study, we will expect you to connect to the Trainerize platform regularly (i.e. weekly) and sync your activity device to the platform. If you do not connect to the Trainerize platform at all over a 2-week period, we will contact you via either phone, Trainerize platform or email to determine the reason for non-compliance. If we are unable to contact you after 3 attempts, we may will withdraw you from the study.

The use of the Fitbit device and the Trainerize application will support the delivery of your exercise prescription and facilitate communication between the study team and you the participant. This communication is important for accurately prescribing the activity program and may directly benefit you by fostering adherence and by allowing you to track your activity progress over time.

Taking part in this study means that you may need to set up 1) a Trainerize application account, and 2) a Gmail/Google account to use the Fitbit device and application, if you are randomized to PAI group. This means that you will need to create a username and password for each application. We will help you with this process, but we will NOT ask you to share these usernames and passwords with the study team. If you have questions about setting up this Trainerize account or Fitbit device, please contact the study principal investigator , Dr. Greg Hundley at [redacted].You will be asked to use the Fitbit device and Trainerize application for the 6-months duration of the study.

You will be asked to share physical activity data such as walking steps per day and whether you have participated in other exercise via the Fitbit device and Trainerize application 3-5 times per week, while you are in the study. This data will be shared with the study team automatically as the Fitbit device syncs with the Trainerize application**.** The Fitbit will continue to collect activity data until the Fitbit is removed/uninstalled/or no longer used. The transfer of this data will require a connection to the internet through either cellular service or personal internet connection. This will be at your own cost. The data you share with the study team will not be monitored by your healthcare provider and only be visible to the study team during the time you are participating in the study. If you have any questions about your health during this study, you should reach out directly to your health care provider(s).

While you are in this study, the Fitbit and Trainerize applications may send auto-notifications. You should not take these notifications as medical advice. The feedback may not be reviewed by the study team or your healthcare provider(s). If you have concerns about your health while you are in this study, or about the notifications you might be getting, reach out to your healthcare provider(s).

You may receive messages from the study team with information we think you should know about your health. If you have questions or concerns about your health information shared in the message, reach out to the study principal investigator Dr. Greg Hundley at [redacted].

You may be required to create an account with Google to participate in this study. Creating an account with Google requires providing personal information. If you do not want to do this or sync

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a personal tracking device to Trainerize, you should not agree to be in this study. When you are no longer taking part in the study or choose to stop using the Fitbit your account will remain open unless you delete your account with Google/Gmail to close the account.

If your own activity tracking device breaks or is damaged, we will provide you with a replacement if we have one available. If the study provides you an activity tracking device and it is broken or damaged, then we will replace it for you.

We will do our best to protect your privacy during this study. When you are no longer taking part in the study your access to the Trainerize application will come to an end. You can continue to use your Fitbit device in your personal capacity as we do not have access to that account or data.

When using the Fitbit which is owned by Google, you agree to the Terms and Conditions set out by the company. We do not have control over how Google will protect your data and privacy. ABC Fitness Solutions, the company that owns the Trainerize application will have access to associated health metrics.

If you join this study, there is a potential risk that data you share may be accessed by someone without your permission or that someone may be able to identify you. These people may misuse the data you share with us in a way that leads to personal harm (e.g., discrimination). There may also be other risks that are not currently known. While we will do our best to protect your data, we cannot remove all risks. In general, there is no additional risk to using the Fitbit device and application or the Trainerize application in this study beyond the risk you take when using any application, you download to your personal phone or computer in your daily life.

Using Fitbit requires that you agree to Google's "Terms of Service" and privacy policy. We do not control these terms and policies, which can change at any time. You should read the Terms of Service and the privacy policies before using Fitbit**.** You should also review your privacy settings often. If any changes are made to Google and Fitbit privacy policies, the research team will not notify you. Google may also collect, store, and sell information you provide through Fitbit. This may include personal information, location data. We do not control whether Google will store or sell your data. We cannot control if they collect more data than the study requires, or how Google will protect your privacy. We will continue to protect the data we collect. However, Google may share or disclose information per their terms and conditions. We have no control over the data they collect or own. Please know that Google may continue to have access to your physical activity data even after you stop being part of the study.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because it is in your best medical interest, your condition worsened,

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new information becomes available, you had an unexpected reaction, you failed to follow instructions, or because the entire study has been stopped.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study. Clinically relevant research results will be disclosed to you if requested. Information that identifies you (name, contact information, MRN) will be removed, not including relevant dates, from the data or specimens that are collected as part of this study and could be used for future research or shared with others without additional consent.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator, Gregory Hundley, MD, at [redacted].

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted].

You will be given a copy of this signed consent form

SIGNATURES:

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature: _____Date: _____Time:_____am pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent:_____Date:_____Time: _____am pm

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