Wake Forest®
School of Medicine

Department of *Health & Exercise Science*

STRENGTH TRAINING AND RUNNING STUDY (STARS)

Informed Consent Form to Participate in Research
Stephen Messier, PhD, Principal Investigator

INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you are a runner. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. 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 study is to determine the effect of strength training in preventing overuse injuries in female runners.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

150 people at one research site will take part in this study. In order to identify the 150 subjects needed, we may need to screen as many as 350 because some people will not qualify to be included in the study.

WHAT IS INVOLVED IN THE STUDY?

If you take part in this study, you will have the following tests and procedures:

Eligibility Visit (SV0): You have come to Worrell Professional Center at Wake Forest University for your first screening visit. The study will be described in detail and you will be asked to sign this consent form. You will be given questionnaires to complete, including training details/history and demographics Also, your height and weight will be measured and your bone density/body composition will be measured via a Dual Energy X-ray Absorptiometry (DXA) scan. This visit will last approximately 1 hour.

Screening Visit One (SV1): . You will return to the Worrell Professional Center at Wake Forest University.The strength and proprioception of your lower body will be measured. This visit will last approximately 2 hours.

Screening Visit Two (SV2): Your completed questionnaires will be reviewed by the study coordinator. You will complete health status questionnaires, your arch index will be measured, and then your lower body flexibility and quadriceps angle will be measured using digital

photography. You will perform a test to evaluate your functional movement which will be filmed. You will then perform tests so we can determine your running mechanics. Your weight will be collected, and a gait analysis (measurement of how you run) and electromyography (measurement of muscle activation) will be performed. This involves videoing you running. The video only records markers that will be placed on your body and does not show a person's actual face or body. Each of the four sites on the leg will be shaved and cleaned thoroughly with a textured alcohol pad to ensure minimal interference. The testing session will last approximately 2.5 hours and will be performed in the JB Snow Biomechanics Lab in Worrell Professional Center of Wake Forest University.

You will be randomized into one of the study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin. You will have an equal chance of being placed in any group.

Group 1:
You will begin coming to the Clinical Research Center (near the undergraduate campus of Wake Forest University) or High Point University, whichever is convenient for you, for exercise classes 2 days per week for about an hour each day. There also is 1 additional recommended day per week. The class will consist of a 10-minute warm-up, a 20-minute strength training period, 15-minutes of neuromuscular (balance/coordination) training, and a 15-minute cool down. These regular exercise classes at Wake Forest will go on for 9 months, followed by another 9 months of follow-up via email and 2 group meetings at Fleet Feet (at months 12 and 15).

Group 2:
You will be observed as you follow your usual run-training routine over the course of 18 months. Emails will be sent to you biweekly for 18 months to update us on your injury/training status. You will attend 5 group meetings at Fleet Feet (at months 1, 3, 6, 12, and 15). After the 18 months, you will be offered a free 6-week strength training program at the Clinical Research Center or High Point University.

After entrance into the study, you will be asked to notify the study staff of your injury status (injured or not injured) via email every two weeks in the case of no injuries, and within 24 hours if an injury occurs. The study staff will contact you if an injury-positive email is received and will determine whether a medical exam is necessary.

Follow-up Injury Visit (FUinjury): If a medical exam is deemed necessary, you will be asked to meet with the study physician, Dr. David Martin, for an assessment. This visit will last approximately one-half hour. An injury report form and an interim training history form will be completed. Health status questionnaires will also be completed. This assessment is free of charge and could possibly include an x-ray or MRI to properly diagnose the injury. The study will pay for the x-ray(s) and/or MRI(s). All runners who sustain an injury will continue to attend follow-up appointments and receive regular follow-up phone calls/emails to assess their rehabilitation. Additionally, injured runners will have the choice of receiving one free physical therapy evaluation for their running related injury. Further evaluation, procedures, and treatment

must be arranged through your own physician and health insurance provider.

9-month Follow-up Visits (FU9): This follow-up will consist of 2 visits lasting approximately 2.5 hours each. The first visit includes completion of an interim training and injury history, summarizing your training/injuries during the past 9 months, a bone density/body composition scan, and measuring your lower body strength and proprioception. The second visit will consist of health status questionnaires, measuring your weight, flexibility, and functional movement, a three-dimensional gait analysis to analyze running mechanics at your preferred training pace, and electromyography. These tests will be completed in the same manner as described in Screening Visits 1 and 2 above.

18-month Follow-up Visits (FU18): This follow-up is similar to the FU9, and will consist of the same 2 visits lasting approximately 2.5 hours each. You will additionally provide a final medication form and meet with the study coordinator for a close-out visit.

As part of this research study, you will be photographed with a digital camera and videotaped during a running test. This is being done to calculate exact measures of your flexibility and assess how you run, done on computerized software. You understand that you may request the filming or recording be stopped at any time during the course of the research study. You can also withdraw your consent to use and disclose the photograph/videotape before it is used. You should also understand that you will not be able to inspect, review, or approve the photographs, videotapes, or other media (including articles containing such) before they are used in this study.

Please choose one of the following regarding the use and disclosure of the photograph/videotape/audiotape used in this research study:

_____ I would like the photographs/videotapes of me to be destroyed once their use in this study is finished.

____ The photographs/videotapes of me can be kept for use in future studies provided they are kept secure and any future study will be reviewed by an IRB. I understand that I will not be able to inspect, review or approve their future use.

We can send copies of your test results to your personal physician. Even if you do not wish to have any of your medical information sent 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 your personal physician?

[ ] Yes [ ] No _____ Initials

How Long Will I Be in the Study?

You will be in the study for about 18 months.

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 to learn about any potential health or safety consequences.

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 muscle or joint soreness following the physical performance required during testing and the exercise program. These symptoms usually subside quickly and are usually not serious. It is possible to have a more serious injury, such as a torn ligament or sprain from these tests and the exercise program, but this is extremely rare. However, these tests and the intervention will be monitored very closely to provide a high degree of safety for you. If you experience any injuries as a direct result of the testing or exercise program, the evaluation, procedures, and treatments will be paid for by the study. In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. 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.

If you participate in this study, you may be exposed to amounts of radiation above what you would normally receive in daily life. This research study involves exposure to radiation from the bone density/body composition scan, and potentially involves exposure to radiation from lower body x-rays. The risk of these procedures are small and is similar to that received from clinical x-ray and nuclear medicine studies. The amount of radiation exposure that you will receive from these procedures is equivalent to a uniform whole body exposure of 199 millirem. This is equal to 0.66 times the amount of background radiation that the average person in the United States receives each year (annual background = 300 millirem). To be sure that you do not receive an unhealthy amount of radiation from your participation in this study, you should let your study doctor know if you have had, or are going to have, any other scans or x-rays as part of your medical or dental care. It is very important that you let your study doctor know if you already are participating in, or plan to participate in, any other research study that involves radiation exposure.

Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

The principal investigator, the institutional review board, and a safety monitor will be reviewing the data from this research throughout the study.

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. The benefits of participating in this study may be increased strength, agility, balance, and coordination.

WHAT OTHER CHOICES ARE THERE?

The tests and exercise program provided are available in the community. This is not a treatment study. Your alternative is to not participate in this study.

What About My Health Information?

In this research study, any new information we collect from you about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes**:** name, address, telephone number, birthdate, and health status.

If this research study involves the diagnosis or treatment of a medical condition, then 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 with Medical Center operations.

We will make every effort 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 computer. Only the following people or organizations will be granted access to your Protected Health Information:

1) The study investigator and his/her staff, or others at Wake Forest University Health Sciences who oversee research

2) Individuals with proper authority at Wake Forest University Health Sciences and Wake Forest University Baptist Medical Center

3) Research Monitor, Kevin Ford, Ph.D., High Point University, and Federal or DoD representatives as part of regulatory oversight activities.

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 for at least six years after the study is finished. At that time any research information not already in your medical record will either be destroyed or it will be de-identified. 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 Dr. Stephen Messier 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:

Dr. Stephen Messier, PhD
[redacted]

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 Wake Forest University 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. This part of the medical record will only be available to people who have authorized access to your medical record. If you are not a patient at this Medical Center, a medical record will be created for you anyway to ensure that this important information is available to doctors 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 website 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 Wake Forest University Health Sciences and North Carolina Baptist Hospital. 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.

WHAT ARE THE COSTS?

If you incur an overuse injury, the assessment by our study physician will be free of charge to you, and the x-ray and/or MRI used to confirm diagnosis (if deemed necessary by the study physician) will be of no cost to you. One free physical therapy treatment and evaluation session will be available at no cost to you. Any other costs beyond that will not be covered by the study. Additionally, costs for your regular medical care, which are not related to this study, will be your own responsibility.

WILL YOU BE PAID FOR PARTICIPATING?

You will receive a $25 gift card to Fleet Feet Sports Winston-Salem upon completion of the 9-month testing visits, and another $75 gift card to Fleet Feet Sports upon completion of the 18-month testing visits.

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 sponsored by Wake Forest University, Wake Forest University Health Sciences, and US Army Medical Research and Material Command. The sponsors are providing money or other support to Wake Forest University Health Sciences to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

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 Dr. Stephen Messier at [redacted] (after 7pm call [redacted]).

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, 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.

This study will be enrolling students from the Wake Forest University and Wake Forest University Medical Center campuses. In addition to your rights as a research participant noted in the previous section, as a student, you are under no obligation to participate in this study. You may refuse to participate or withdraw from the study at any time and for any reason without affecting your grades, performance evaluations, or assignments. You will not be pressured into participating in this research study by any statements or implied statements that your grades, performance evaluations or assignments will be affected by your willingness to enroll in the study. Your medical records/information will not be used by the faculty, administration or study staff to make decisions regarding the status of your medical benefits. If you have questions regarding your enrollment in the study and your status as a medical student, please contact the Office of Student Services for additional information.

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 coordinator, Monica Love at [redacted], or the principal investigator, Dr. Stephen Messier at [redacted] (after 7pm call [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 Name (Printed):_____

Person Obtaining Consent (Signature):_____Date:_____ Time:_____ am pm