

HUMAN SUBJECTS INFORMED CONSENT

Omnibus Running Protocol

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Purpose/Description of Research

You have been invited to participate in this study because you are a runner between the ages of 18-50, in good health and are able to run overground and/or on a treadmill. To be included, you must currently be running a minimum of 6 miles per week, between the ages of 18 and 50, and be familiar with treadmill running if participating in a treadmill running protocol. Your participation will involve one testing session which should be approximately 1 hour and 30 minutes in duration. We will be collecting data to examine the way your body moves and the forces that are caused by your legs during running on a treadmill and/or overground.

The investigator will indicate, by checking in the right margin, which of the following testing protocols applies to you. Please initial in the right margin after you have read over the protocol and consent to your participation.

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For this study we are comparing: _____

The investigator will indicate, by checking in the right margin, which of the following running protocols applies to you. Please initial in the right margin after you have read over the protocol and consent to your participation:

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1) **Overground Running:** The data collection will take place in the Motion Analysis Laboratory in the Department of Physical Therapy at the University of Delaware. You will be supplied with a pair of running shoes to wear during the data collection. You will then be asked to run along a 75-foot runway at a prescribed speed. We will only accept trials that are run at the prescribed speed +/-5%. The prescribed speed will be in the range of 2.68-4.47 meters/second (6.0-10.0 mph). We will record your speed for each trial and provide verbal feedback to help you keep it within the speed range for this study. Ten trials will be collected. It is possible that you will be required to run across the lab more than 10 times in order to obtain the ten acceptable trials.

Indicated
Protocol: _____

Subject
Initials: _____

2) **Treadmill Running:** The data collection will take place in the Instrumented Treadmill Laboratory in the Department of Physical Therapy at the University of Delaware. You will be supplied with a pair of running shoes to wear during the data collection. You will be asked to run for up to 10 minutes as we collect data. The prescribed speed will be in the range of 2.68-4.47 meters/second (6.0-10.0 mph). Treadmill speed will be controlled by the investigator. The treadmill may be halted at anytime by either you or the investigator via emergency stop buttons.

Indicated
Protocol: _____

Subject
Initials: _____

The investigator will now check in the right hand margin which of the following testing methods will be utilized for this data collection. Please initial in the right hand margin where indicated after you have read the indicated section(s):

a) **Running Shock Analysis:**

A small device measuring shock will be placed on the subject's leg just above the ankle. We will then ask you to complete the running protocol as described above.

Indicated
Protocol: _____

Subject
Initials: _____

b) **Running Force Analysis:**

First, we will have you stand on a plate in the lab floor or on the treadmill and record a data trial. Then we will ask you to perform the running protocol as described above.

Indicated
Protocol: _____

Subject
Initials: _____

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c) **Running Motion Analysis:** Reflective markers will be placed on your lower legs. Next, we will have you stand on a section of the treadmill or the lab floor in view of eight cameras and record a data trial. We will then ask you to complete the running protocol as described above.

Indicated Protocol: _____
Subject Initials: _____

d) **Running Muscle Activity Analysis:** Sensors will be placed on your skin to detect the electrical activity in your muscles. The sensors are 1.5 in. x 0.75 in. x 0.25 in. Before the sensors are placed on your leg, small areas of your leg will be shaved with a new disposable razor. Next your skin will be wiped with a paper towel to brush away hair and dead skin cells. Then your skin will be wiped with rubbing alcohol so that the sensors make good contact with your skin. Tape and elastic bands will be used to hold the sensors in place. We will then ask you to complete the running protocol as described above.

Indicated Protocol: _____
Subject Initials: _____

e) **Running Video Analysis:** Digital video will be collected of your running motion. Your anonymity will be preserved by video taping from the shoulders to your feet. We will ask you to complete the running protocol as described above.

Indicated Protocol: _____
Subject Initials: _____

Data Storage

Information and measurements obtained from you during this study will be kept confidential. For data storage purposes, you will be identified by code number. Only personnel working in collaboration with Dr. Irene Davis and the human subjects review board are permitted to view the research records. Data may be used for publication purposes, but a code number will be assigned to your data in order to maintain confidentiality in reporting results. After the study is over, the data will be stored indefinitely for future reference, with confidentiality maintained.

Conditions of Subject Participation

Your participation will be stopped if you are unable to run at the prescribed speed and/or duration during data collection. If at any point you do not wish to continue, you may stop the testing session. You do not need to provide a reason to stop your participation.

In the event of physical injury as a direct result of the research procedures in the University of Delaware Motion Analysis Lab and/or Instrumented Treadmill Laboratory, you will receive first aid. If you require further medical treatment or desire further medical care, you will be responsible for the cost.

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Risks and Benefits

It is possible that you could slip, trip, or fall while on the treadmill or running through the laboratory. However, we will take precautions to reduce the chance of those things happening to you. Treadmill speeds will be increased and decreased gradually. The treadmill has a handrail that you can grab to steady yourself, and there is an emergency stop button on the handrail that you can push to stop the treadmill. There will be two people present to collect the data and monitor you during the study. The investigators will have the ability to stop the treadmill immediately in the case of an emergency. It is unlikely, but possible that you may have some mild irritation from the tape adhesive on your skin.

You will not receive any benefits due to your participation in this study.

Contacts

If you have any questions regarding this study, you may contact Dr. Irene Davis, Dept. of Physical Therapy (302-831-4263). If you have any questions regarding your rights as a research subject, you may contact the Chair of the Human Subjects Review Board in the Research Office at the University of Delaware (302-831-2136). You will receive a copy of this explanation and consent form to retain for your records.

Compensation

You will be paid \$25 for each testing session you participate in.

Assurances

The project in which I have been invited to participate has been explained to me, and all of my questions have been answered to my satisfaction. My participation in the project is voluntary. I understand that I may stop my participation in this study at any time; no explanation will be required of me, and there will be no penalty for my withdrawal from the study. I have read and understand the explanation of the procedures to be used. I certify that I am currently injury free and do not have any illness or other medical condition that will interfere with my ability to participate as outlined above.

Only personnel collaborating with Dr. Irene Davis and research office staff are permitted to view the research records. However, I have been informed that a code number will be assigned to my data in order to maintain confidentiality in reporting results. I understand that my data will be stored indefinitely for future reference.

Subject Name (Please Print)

Subject Signature

Date

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Subject Initials: _____

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