University of North Texas Health Science at Fort Worth

COMBINED LAY SUMMARY/INFORMED CONSENT

Title: [redacted]

Principal Investigator: [redacted]
Collaborating Investigators: [redacted]

Subject Name (please print)_____

Study Purpose:
The goal of this project is to determine how your blood pressure is controlled during exercise. There are many different factors that can influence blood pressure control during exercise and this study will greatly help our understanding of this area.

Procedures:

Overview

You will be one of twenty-four (24) subjects recruited to participate in this study. This study will involve you exercising while being monitored by several non-invasive devices. In addition, the study will use a catheter (tube) inserted into an artery in your arm for other measurements. We are primarily interested in your blood pressure, heart rate and leg blood flow. It will involve two visits on two separate occasions, which will be at least 5 days apart. On the first visit, if you agree to participate, you will sign this informed consent. During that visit,
we will also ask you to complete a medical history questionnaire. If you are a woman, you will be asked to take a urine pregnancy test to ensure that you are not pregnant. Due to risk and

Initial_____ Date_____

scientific design reasons, pregnant women cannot be in this study. You will then be familiarized with the equipment and procedures and you will then perform a maximal exercise test. Altogether, this will take approximately 1-3 hours.

The second visit is based on the first visit and you will be invited to come back for this session if:

- you are not pregnant (if a woman);
- no complications were associated with your maximal exercise test on that first visit;
- completion of the medical questionnaire identified no health issues; and
- your neck anatomy allows proper stimulation by the neck collar during your familiarization.

In Visit 2, you will do three 30-minute exercise protocols, with at least 30 minutes rest between each period of exercise. This will take between 4-7 hours. Thus in total, your involvement over the two visits will be between 5 and10 hours.

Visit 1 Details

During your first visit we will record your height and weight. Electrodes will be attached to your chest so that we can monitor your heart's rate and rhythms. We will also measure your blood pressure by placing a cuff around your upper arm, this cuff will automatically inflate and deflate while it is measuring your blood pressure. If everything appears normal, we will ask you to perform a *maximal exercise stress test* using a single-leg kicking ergometer (leg kicking bike chair). An ergometer is a piece of equipment used for measuring the amount of work performed while exercising. In addition, the maximal exercise stress test will determine your maximal kicking power. This is a novel form of exercise using a specially designed chair and bicycle ergometer. The amount of effort you have to use to kick the lever can be increased or decreased. We will ask you to perform a maximal exercise test where you will kick at a set rate of 60 kicks per minute. This exercise test will start off at a very easy work load and will then increase every 3 minutes until you are unable to continue at the given rate of 60 kicks per minute.

After the maximal exercise stress test, you will remain in the laboratory to practice the procedures that will be used when you come again for the second part of the study (Visit 2). The purpose of this practice session is to familiarize you with the experimental procedures so you

Initial_____ Date_____

will feel confident, relaxed, and informed about what happens during the studies on Visit 2. You will already be familiar with the leg-kicking exercise from the maximal exercise stress test. We will also familiarize you with three new things: the hand-held devices which we will be use to measure leg blood flow and cardiac output (blood flow out of your heart each minute), the neck pressure collar, and the feeling of wearing the anti-G or Medical Anti-Shock (MAS) trousers while leg-kicking. These techniques will be described in more detail later.

Visit 2 Details

If you are not invited to return for the second session of the study you will be compensated according to a prorated schedule of $15 per hour. If this is the case, the form for compensation will be submitted at the end of session one. If invited however, you will return to the lab for the second session of the study. Visit 2 will begin with you being fitted with the same sensors for heart rate measurements. After the sensors are in place, [redacted], a board certified cardiothoracic surgeon, will begin inserting a small, plastic, flexible tube called as catheter into an artery in your arm called your brachial artery, this catheter will be used to measure blood pressure. [redacted] will begin by injecting you with a solution which will numb the area and reduce the discomfort of putting in the tube. You will feel a stick like you do when you get blood drawn while at the doctor's office. While [redacted] is putting in the tube you may feel some discomfort, but it should be minimized by the numbing solution. The catheter will be connected to a bag which contains a salt water solution and a drug called heparin. The heparin is used to help prevent blood clots from forming. Any pain should go away once the tube is in place. After the insertion of the catheter you will put on special pants known as MAS trousers (pants) and sit on the seat of the leg-kicking ergometer. The MAS pants are similar to those used by jet fighter pilots. They can be worn over normal pants or shorts. These specially designed pants have pockets which air can be pumped into through tubes. When air is pumped in, they inflate and exert external pressure onto the legs. While wearing these pants, you will perform three different exercise conditions with a minimum of 45 minutes resting recovery (or until your heart rate and blood pressure have returned to resting values) between each condition. In each exercise condition, the following measurements will be taken: leg blood flow, cardiac output (the amount of blood pumped of your heart every minute), heart rate/rhythms, blood pressure and an estimate of the volume of blood in your chest. All of these measurements will be measured

Initial_____ Date_____

using hand-held non-invasive recording devices, as well as measurements from a catheter (tube) to be inserted into your arm.

Each of the three exercise conditions will consist of three different exercise intensities each lasting 10 minutes. Therefore, the total amount of time of each condition will be 30 minutes plus 45 minutes rest. The exercise involves single-leg kicking while sitting on a customized ergometer. Three levels of difficulty will be used which will correspond to 30%, 50% and 75% of your maximum power (this was determined for you on your first visit to the laboratory):

- In the first condition, you will perform the leg-kicking exercise while wearing the MAS trousers *but without them inflated*.
- In the second condition, you will perform the leg-kicking exercise *with* the MAS trousers inflated. The trousers will be inflated to a pressure that will restrict blood flow into the leg a small amount, so it feels like a firm pressure is being applied to your legs. The pressure of the MAS trousers will not be painful, but you will feel a definite tightness around your legs.
- In the third condition, you will again do the leg-kicking exercise with the MAS trousers inflated. In addition, air pressure will be applied to your neck through a neck collar which will fit around the front two-thirds of your neck.

Here are the Measurements we will use in this Study:

Electrocardiogram: Sensors will be placed on your chest with sticky material. These sensors will monitor your heart's rate and rhythms continuously during the experimental procedures. There is no known pain or risk associated with this measurement.

Blood Pressure (invasive): On the second visit your blood pressure will be measured by a small tube in your arm (brachial arterial catheter) that will be placed there by [redacted].

*Blood Pressure (non-invasive)***:** Blood pressure will be measured non-invasively by a small cuff placed around your middle finger and a larger cuff placed around your upper arm, which will inflate and deflate while it is measuring your blood pressure. There is no known pain or risk associated with this measurement.

Initial_____ Date_____

Measurement of leg blood flow: We will require you to wear loose shorts which can be rolled up so that the upper thigh and groin area can be reached. This measurement uses a hand held device which will be placed in the crease of your leg, near your groin area, to measure blood flow going into your leg. This is a routine standardized measurement used to assess blood flow into the leg. It is a non-invasive measurement with no known pain.

Measurement of the amount of blood pumped out of your heart every minute (Cardiac Output): This measurement is assessed using the same technique as the leg blood flow measurement, but in this case, it is used to measure blood flow coming out of your heart. A device will be placed on the outside base of your neck near the hollow of your throat in order to obtain this measurement. There is no known pain or risk associated with this measurement.

Neck Pressure: A lightweight, flexible collar will be placed around the front two-thirds your neck. This forms a closed space or chamber around the front and side of your neck, air is then pumped into this area through tubes, allowing an external pressure to be applied to the area inside the collar. This collar will apply pressure to your neck during some of the exercise conditions. By performing this measurement, we will be able to look at the function of certain pressure receptors in your neck. This may be a little uncomfortable but there is little or no known risk. It is a standard measurement technique used to assess blood pressure control in this laboratory.

Measurement of the changes in blood volume in your chest: Two sensors will be placed on your neck, along with two additional sensors placed underneath your armpit. These sensors will be connected to a box, which will measure changes in the volume in your chest. This is a non-invasive experimental procedure and is associated with no known pain or increased risk.

Risks and Discomforts

There is a certain amount of risk that is involved with participation in any research study. However, every precaution will be taken during the study to ensure your safety in this study. Some of the most likely potential risks are listed below.

Initial_____ Date_____

Brachial Artery Catheterization (plastic tube in your arm): The major risks of the brachial catheterization involve the increased risk of blood clot formations, puncturing of your artery during catheterization, and/or chance of infection. An additional risk may be the possible long term complications with the drug Heparin. This drug is used to try and ensure that no blood clots form during the study and that anemia (the loss of red blood cells) is minimized. Some bruising and/or tenderness may be felt after the catheter has been removed.

[redacted]…add some language in here from the protocol that addresses some post-catheter recovery issues (daily call-backs, check for bruising and swelling, etc.)

Exercise Stress Test: In performing exercise to fatigue, there are certain risks that exist. These risks may include abnormal increases or decreases in blood pressure, irregular heart rhythms, and in rare instances even heart attack or death. The death rates that occur in maximal exercise testing are about 1 in 10,000. The risk of a serious problem occurring is between 2 and 24 out of 10,000 in patients with heart disease or in elderly participants. In healthy people, the risk of such an occurrence is very low. During the fitness test your heart rate, heart rhythm, and blood pressure will be continuously monitored.

This Exercise Stress Test is a very routine procedure that we perform in almost every study we conduct in our laboratory. To date, our track record with this procedure has been excellent. You should know that, over the years, a few subjects have felt nauseous (sick to their stomach) after this procedure, although that has not been a typical response.

Restriction to blood flow: There may be some discomfort or feeling of unusual pressure when the MAS pants are inflated, but the pressure is low so that flow into the leg will not be impeded. This is a non-invasive experimental procedure and is associated with no known pain or increased risk.

Neck Pressure: Other than minor difficulties in swallowing while the neck collar is applying pressure and/or possible lightheadedness/dizziness, there are no known risks associated with this measurement. If at any time you experience any uncomfortable feelings, you must let the investigator know immediately.

Initial_____ Date_____

Throughout the study, at least one person will be watching you at all times to see how are doing and ask how you are feeling. During testing your heart rate and blood pressure will be monitored and immediate feedback of these measurements will provide us with instant information so we can decide on your ability to continue the study. In general, we will instruct you in the proper experimental procedures to follow in order to minimize any problems associated with these procedures.

In case of any emergency, specific laboratory personnel are trained in CPR and the use of Automated External Defibrillators (AEDs). If an emergency arises, we will immediately contact campus police at extension 2600 and request emergency personnel to be dispatched to the laboratory, and begin basic CPR if necessary. In addition, a physician, licensed to practice in the state of Texas, will be on call or otherwise available during the procedures. In the 30 years this laboratory has been conducting research of this type, there have been no cases where study team members needed to notify the campus police because of an emergency situation.

In our experience of maximal exercise testing, neck pressure, chest volume studies cardiac output and the other measurements listed in the measurements section; there is no known increase in risk of performing all these measurements together in the same study. Although the increase in effects may not be known, our experience has demonstrated that the effects of all the measurements performed together are probably very minimal. We routinely use all of these measurements in our laboratory without any reports of adverse effects occurring.

Follow-Up

After completing the study, you should call us if you have any problems or health issues that you think might be related to being in this study. Also, we will contact you every day for the next week after the second session (Visit 2) to see if you have any questions, concerns, or complications that might be connected to the study.

Pregnancy (only women need to read this section):

If you are pregnant or contemplating pregnancy while you consider your participation in this study, you will not be allowed to participate in this study. Women will be asked to take a urine pregnancy test to ensure that they are not pregnant.

Initial_____ Date_____

Contacts

If you have any questions or concerns regarding the research study or any effects that you may experience following the experiments, [redacted] may be reached 24 hours a day at [redacted]. If you have any questions and/or problems concerning the brachial (arm) catheterization you should call [redacted]. [[redacted]…make sure this is a "live" phone number and not an answering machine or voice mail tree]. If you have any questions or concerns regarding your rights as a research subject, you should contact XXXXXX, Chairman of Institutional Review Board at the University of North Texas Health Science Center at Fort Worth. XXXXX may be reached at 817-735-XXXX. You can also contact the Office for the Protection of Human Subjects (OPHS) at 817-735-0409. Please ask questions if you do not fully understand the explanation of the objectives and risks involved in this study.

Benefits:

You will gain no direct benefit from your participation in this study. The scientific community may gain a greater understanding of cardiovascular control during exercise, which may potentially provide insight into exercise related complications such as sudden cardiac death and post-exercise low blood pressure.

Subject Compensation

You will be compensated for your time and effort to a maximum of two hundred dollars ($200) following completion of the testing. If you do not complete the testing for any reason such as lack of interest, you want to withdraw from the study, the researchers decide to stop your participation in the study, etc., you will be compensated according to a prorated schedule of $15 per hour. As applicable, payments to you may be withheld and credited to any outstanding debts you may have with the University of North Texas Health Science center at Fort Worth or the State of Texas.

Confidentiality:

Your records will be kept as confidential as possible under current local, state, and federal laws. However, personnel from federal regulatory agencies and members of the Institutional Review Board may examine your records and study data. In case the final study data should be prepared for publication, your name will not appear in any published material.

Initial_____ Date_____

Your personal medical information may be reviewed by the principal investigator, physicians, and research assistants working on this study. Individual subject data and information will not be identified in the analysis of data or in subsequent publications of the results.

COMPENSATION FOR INJURY:

We at the university of North Texas Health Science Center (Fort Worth) have not set aside any money for financial compensation nor are we able to absorb the costs of medical treatment should you be injured as a result of your participation in this research. If required, medical care will be made available to you in the case of such injury, but you (or your private insurer, Medicare, Medicaid or other governmental healthcare program) will be responsible for the expense of any medical care, including hospitalization, that is needed.

You should know that by signing this form you are neither waiving any of your legal rights against nor releasing the principal investigator, the University of North Texas Health Science Center at Fort Worth or any of their respective agents from liability for negligence with respect to the conduct of this study. If you are injured and feel that your injury justifies pursuing a legal remedy, you have the right to do so.

Leaving the study

You can choose not to continue in the study or authorize use and disclosure of your health information any time without penalty or loss of benefits that you are otherwise entitled. If you decide to revoke your authorization to use or disclose your health information, you will not be allowed to continue in the study. Additionally, you may be removed from the study for reasons of but not limited to: failure to follow instructions, occurrence of side effects, or a severe worsening of a medical condition. If you decide to withdraw from the study, the study personnel may only use and disclose your health information already collected.

If you are a student or employee of the University of North Texas Health Science Center, your participation (or non-participation) will in no way affect your academic standing or employment status.

Initial_____ Date_____

Consent

I voluntarily agree to participate in this study. I have read and have been told the description of the techniques, including the possible risks involved and the use and disclosure of medical information. I have been given the opportunity to ask questions and discuss the study. I have been told that I may withdraw from the procedure at any time. I have been told that I will be able to request and receive all information pertinent to me. I will receive a copy of this informed consent document.

_____ _____

Signature of Participant Date

_____ _____

Signature of Person Obtaining Consent Date

Initial_____ Date_____

Protocol Title: [redacted]

Principal Investigator: [redacted]

ADDENDUM TO CONSENT FORM FOR PARTICIPATION IN A RESEARCH STUDY(HIPAA AUTHORIZATION FOR USE OF PROTECTED HEALTH INFORMATION IN RESEARCH)

The word "you" means both the person who takes part in the research, and the person who gives permission to be in the research. This form and the attached research consent form need to be kept together.

Purpose of this form:

You have been asked to take part in a research study. The consent form for this study describes your participation, and that information still applies. This extra form is required by the federal "Health Insurance Portability and Accountability Act" (HIPAA). The purpose is to get your permission (authorization) to use health information about you that is created by or used in connection with the research. If you are signing on behalf of someone other than yourself, this permission applies to that person's health records.

Authorization to Use Health Information:

The investigator(s) named above and their assistants will be allowed to see and to use your health information for this research study. We may share your health information with people at the Health Science Center who help with the research.

We are asking you to take part in the research described in the attached consent form. To do this research, we need to collect health information that identifies you. The information we might use or disclose includes but is not limited to electrocardiograms, blood pressure recordings, heart rate, stress test results, data recorded from the following measurements: leg blood flow, cardiac

Initial_____ Date_____

output, neck pressure, thoracic impedance, and/or any health information collected during the study.

For you to be in this research, we need your permission to collect and share this information.

Term of Authorization:

If you sign this form, we will collect your health information until the end of the research. We may collect some information from your medical records even after your direct participation in the research project ends. We will keep all the information as long as necessary, in case we need to look at it again. We will protect the information and keep it confidential.

Refusal to sign/Right to Revoke:

If you sign this form, you are giving us permission to collect, use and share your health information. You do not need to sign this form. If you decide not to sign this form, you cannot be in the research study. You need to sign this form and the attached consent form if you want to be in the research study. We cannot do the research if we cannot collect, use and share your health information.

If you change your mind later and do not want us to collect or share your health information, you need to send a letter to [redacted] listed on the attached consent form at 3500 Camp Bowie Blvd., Ft. Worth, Texas 76107-[redacted]. The letter needs to say that you have changed your mind and do not want [redacted] to collect and share your health information. You may also need to leave the research study if we cannot collect any more health information. We may still use the information we have already collected. We need to know what happens to everyone who starts a research study, not just those people who stay in it.

Questions regarding your privacy rights:

Any questions? Please ask the researcher. You can also call 817-735-[redacted] with questions about the research use of your health information. The researcher will give you a signed copy of this form.

Initial_____ Date_____

SIGNATURE, DATE, AND IDENTITY OF PERSON SIGNING

By signing this form, I am giving permission for the personal health information about _____**(please print your name here)** to be collected and used as described above by the researchers and staff for the research study described in this form and the attached consent form. I will be given a copy of this authorization form after I have signed it.

Signature: _____ Date: _____

Initial_____ Date_____