

SHORT FORM CONSENT

ORAL PRESENTATION/SCRIPT - EXAMPLE

For the project “Exercise, Heat Stress, Lung Function, Cognitive Problem Solving and Their Relationship to Academic Achievement” (Dr. Researcher of the Department of Phrenology at Texas Tech, 742-XXXX), the following summary explains how the elements of consent are explained to subjects.

Purpose

Understanding the relationship between exercise and the ability to solve problems.

Understanding the possible role of lung functioning and stress on the body due to heat in this process. Compare the test performance with academic records, including GPA and entrance test scores.

Understand some of the effects of stress from heat on both physical (e.g., lung functioning) and cognitive functions (e.g., solving complex problems).

Procedures

- **Interview:** In the first step in this research, you will fill out a questionnaire about your health and be interviewed about your health by trained professionals before any tests. In the course of the interview they will determine if there are any reasons that would make it unsafe for you to take the test. Consequently, it is important that you provide complete and accurate answers to the interviewer. Any failure to answer completely and honestly could lead to possible unnecessary injury during the test. Also, if you think there is any reason you should not participate in a study that involves physical stress in hot conditions, you must inform the interviewer.
- **Pulmonary and graded exercise tests:** The second step, which will take place today, is a set of tests of your lung functioning. To start, standard pulmonary function testing will be performed to demonstrate normal lung function. To do these tests you will have to inhale and exhale into a tube several times as hard as you can. Second, a graded exercise test on a stationary bicycle will be performed. You will continue to exercise until you tell the operator that you feel fatigue, shortness of breath, or chest discomfort. During the test, expired respiratory gases will be collected in order to determine your maximal oxygen consumption. Your blood pressure will be taken prior to and during the test with a standard blood pressure cuff. Your heart rate and rhythm will be monitored during the test with a standard electrocardiograph. This requires attaching electrodes to your chest with tape.
- **Monitoring:** During the test itself, a trained observer will monitor your responses continuously and take frequent readings of blood pressure, the electrocardiogram, and your statements about your effort. A true determination of your exercise capacity depends on continuing the test to the point of fatigue (when you tell the operator to

stop) or reaching a pre-determined exercise stopping point (when the operator tells you to stop) It is important to remember to tell the operator to stop the test at any point if you feel unusual discomfort or fatigue. Following the test, you will be monitored for approximately 10 minutes to insure the heart rate and blood pressure have returned to pre-test levels. The questionnaire and interview should take about 30 minutes and the exercise test about 45 minutes for a total of about an hour and 15 minutes.

- Second exercise test and heat manipulation: The third step in the research will take place in another session two days from today. You will be asked to ride the exercise bike for endurance at about 55-60% of the exercise intensity that you reached on the first test. This level of exertion should produce respiratory muscle fatigue (labored breathing) but will fall short of the level of exertion you got to in the first test. You will perform this second test in either hot (100 degrees Fahrenheit, 45% humidity) or normal (70 degrees Fahrenheit, 45% humidity) conditions. Otherwise this second test will be exactly like the first test. It will end when you are no longer able to breathe at 85% of your maximum oxygen consumption.
- Cognitive tests: The last step in the research will be a test of your performance on a test of thinking ability. Immediately after you finish the exercise, you will sit at a computer and do a series of tasks that require you to do such things as respond quickly to identify characteristics of words, or find associations between words, or determine whether briefly presented strings of letters are words or not. During this test your breathing, heart rate, and blood pressure will continue to be measured just as they were during the exercise test. The second session should take about an hour and a half altogether, 45 minutes for the exercise task and 45 minutes for the cognitive tests.

Academic Records: Finally, because we want to compare your performance on the cognitive tests with your academic record, we are asking you to give us permission to obtain information on your grade point average and your entrance test scores.

Risks

Due to the extensive exercise, you will feel tired and may experience muscle soreness.

The blood pressure cuff and attaching or removing the electrodes from your skin may make you uncomfortable.

During the actual exercise tests there is a very small possibility for healthy individuals of more serious effects. These could include:

- abnormal blood pressure
- fainting
- disorders of heart rhythm
- stroke
- heart attack or even death in very rare instances

Precautions: Every effort will be made to minimize these occurrences by precautions and observations taken during the test. Oxygen and trained CPR personnel will be available on

site during all exercise tests. You should consider these risks when you decide whether or not be a subject in this research.

Benefits

1. Learning something about exercise testing
2. Course credit: If you are enrolled in (class), you will receive 5 extra points on the third examination. The instructor will offer you a chance to earn the same credit in an activity that involves about the same time and effort but that does not involve research.

Confidentiality

Access: Data and your academic records seen only by Dr. Researcher and her assistants. All the records will be kept in Dr. Researcher's laboratory in a locked file cabinet. Only those working on this project will have access to that cabinet.

Recording and storage: Once all the data are recorded and entered into a computer, you will be identified only by a code and anything with your name on it, except a copy of this consent form, will be destroyed.

Publication: If any of the findings from this study are published, your name will not be used.

Rights and Information About Consent

Voluntary participation: You will not lose anything to which you are entitled by refusing to participate.

Withdraw from the study any time you want, even in the middle of a test. If you do withdraw, and you are in a (class) you will receive proportionate credit toward your grade on the third examination.

Staff may discontinue participation: If they believe that there is a risk to you based on their observations or measurements. You will be referred for medical examination and treatment if this occurs.

If you decide to withdraw: You may be required to keep the monitoring equipment in place for enough time for the staff to ensure that you have not been harmed by the tests.

New information and unforeseeable risks: If we obtain information during this study that changes our assessment of the risks involved or if we find any other information that might affect your willingness to continue with the study, we will inform you.

Contact and Insurance Information

Dr. Researcher will answer any questions you have about the study. For questions about your rights as a subject or about injuries caused by this research, contact the Texas Tech University Human Research Protection Program. Refer to contact information on short form consent document.

If this research project causes physical injury, Texas Tech University or the Student Health Services, may not be able to treat your injury. You will have to pay for treatment from your own insurance. The University does not have insurance to cover such injuries. Refer to contact information on short form consent document.

Signature of Witness to Oral Presentation

Date

Signature of Investigator Conducting Consent Process

Date

This consent form is not valid after **Month/Date/Year**.