

The following information is provided as a sample informed consent form. Researchers also need to review the information related to the Institutional Review Board for Human Subjects on the University of Montevallo (HASRC).

#### Informed Consent

Title of Research: Do VO<sub>2</sub> levels affect the results of a tennis match?

Investigator: John Doe, Ph.D.

Before agreeing to participate in this research study, it is important that you read the following explanation of this study. This statement describes the purpose, procedures, benefits, risks, discomforts, and precautions of the program. Also described are the alternative procedures available to you, as well as your right to withdraw from the study at any time. No guarantees or assurances can be made as to the results of the study.

#### Explanation of Procedures

The purpose of this research study is to determine the maximal oxygen consumption (VO<sub>2</sub> max) levels in tennis players and determine if a relationship exists between wins and losses. Each subject will be required to conduct one exercise test. A VO<sub>2</sub> max test will be conducted on a motor-driven treadmill. The treadmill test will last 30 minutes and be conducted in the XYZ Room at the XYZ Center.

A mouthpiece with a one way re-breathing valve attached to a breathing tube will be used to collect air samples during the exercise test. Essentially, subjects breathe room air through a mouthpiece, and then expire their air into a tube that connects to a machine. This machine analyzes carbon dioxide and oxygen content, which allows the researchers to calculate the amount of oxygen used by the subject under resting and exercise conditions. A test is considered valid when two of the following three conditions are met: (1)

predicted maximal heart rate is obtained (measured by a Polar Vantage XL Heart Rate Monitor<sup>®</sup> chest strap and watch), (2) the respiratory exchange ratio reaches 1.15 or higher, (3) or oxygen consumption plateaus. Verbal encouragement will be given to help subjects achieve a valid exercise test. To assess VO<sub>2</sub> max directly, an individual's expired air is measured during exhaustive physical work.

The workload is gradually increased on the treadmill by increasing the speed, raising the slope, or both. As the workload increases, oxygen consumption also increases. Throughout the test period exhaled air is collected using a spirometer. When the participant can no longer continue, the test is stopped. Maximal oxygen uptake is obtained when the increased workload is no longer accompanied by an increase in oxygen uptake. The exercise bout for the maximal oxygen consumption test consists of running at a speed of between 1 mph and 10 mph (depending on the ability of the subject) through a series of stages, with a modest increase in workload at each stage. Blood pressure will be measured at the end of each stage. Heart rate data will be recorded continuously.

Before and after completing the treadmill test, participants will be required to complete a "warm-up" and "cool-down" session including stretching exercises. Each session will last approximately 15 minutes. In addition, participant's win-loss record will be recorded for the duration of the spring 2003 tennis season.

#### Risks and Discomforts

As with any exercise test, certain risks and discomforts may apply. The risks involved in this exercise test may include abnormal blood pressure, fainting, disorder of heartbeat, and in the most extreme instances, heart attack, stroke, or death. Every effort will be made to minimize these risks by selecting only highly conditioned subjects and by continuously monitoring participants throughout exercise testing. It is the participant's responsibility to inform the study investigator if you feel dizzy, ill-feeling or other symptoms during or after the treadmill test.

Participant's initials: \_\_\_\_\_

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Following American College of Sports Medicine guidelines for exercise testing, the exercise test will be stopped if any of the following conditions happen: onset of chest pain; drop in systolic blood pressure with increasing exercise intensity; signs of poor circulation, including pallor (changes in skin color), cyanosis (blue skin), or cold and clammy skin; severe shortness of breath; vertigo or confusion; leg cramps; or intermittent claudicating (blood clotting that can cause intense leg pain), increased blood pressure (systolic blood pressure [SBP] > 260 mmHg; diastolic blood pressure [DBP] > 115 mmHg). First aid and an automated external defibrillator (AED), along with CPR and AED certified personnel, will be on hand to treat any problems that may arise.

### Participants Responsibilities

Participants should report any information regarding his/her individual health status that may affect the safety of exercise tests, or previous experiences of unusual feeling with prolonged physical exercise. Any unusual feeling associated during this exercise should be immediately disclosed to the testing personnel.

### Benefits

Although there are no direct benefits to the people in this study, possible benefits include better equipping participants to perform sports at an optimal level. In addition, knowledge concerning the relationship between VO<sub>2</sub> max and win-loss record may be beneficial to the general public and amateur or professional tennis players.

### Alternative Procedures

Because this study does not involve specific treatments or procedures, there are no alternative treatments to participating in this study.

### Confidentiality

All information gathered from the study will remain confidential and kept in a locked draw. Participant's individual scores will not be disclosed outside of the testing personnel without each participant's written permission. However, the University of Montevallo IRB may review the study data without written consent. The results of this study may be published for scientific purposes, and participant's identity will not be revealed.

### Withdrawal Without Prejudice

Participation in this study is voluntary; refusal to participate will involve no penalty. Each participant is free to withdraw consent and discontinue participation in this project at any time without prejudice from this institution.

### Costs and/or Payments to Subject for Participation in Research

There will be no costs for participating in the research. Also, participants will not be paid to participate in this research project.

### Payment for Research Related Injuries

The University of Montevallo has made no provision for monetary compensation in the event of injury resulting from the research. In the event of such injury, UM will provide assistance in locating and accessing appropriate health care services. The cost of health care services is the responsibility of the participant.

Participant's initials: \_\_\_\_\_

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Questions

Any questions concerning the research project and/or in the case of injury due to the project, participants can call Dr. Mary Que (faculty advisor for this project) at 205-726-XXXX. Questions regarding rights as a person in this research project should be directed to name (please place name of current IRB chairman here), the University of Montevallo Institutional Review Board Chairman, at 205-665-6444.

Agreement

This agreement states that you have received a copy of this informed consent. Your signature below indicates that you agree to participate in this study.

\_\_\_\_\_  
Signature of Subject

\_\_\_\_\_  
Date

\_\_\_\_\_  
Subject name (printed)

\_\_\_\_\_  
Signature of Researcher

\_\_\_\_\_  
Date

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