## **COLORADO MESA UNIVERSITY**

## **INFORMED CONSENT SUMMARY**

This summary is an overview. Please read the entire consent form before you make a decision. If you have questions later, the contact information for the primary research investigator in charge of the study is below.

**TITLE OF PROJECT**

**Assessment of Mitochondrial Function via Blood Lactate Response to Exercise**

**STUDY SUMMARY**

You are invited to participate in a research study. Taking part in this research is voluntary and you can withdraw at any time.

**Purpose**The purpose of this study is to compare two different maximal exercise testing protocols, and the effect that each has upon lactate production.

**Procedures**If you choose to participate in this study, you will be asked to undergo body composition analysis to measure bodyfat and fat-free mass. This procedure will require you to wear a tight-fitting garment, such as a spandex bathing suit. This test should not exceed 15 minutes. You will also complete two maximal effort aerobic tests, each session scheduled one week apart, lasting approximately 30 minutes, using a stationary bicycle. During each test you will have small samples of blood drawn at several points. This test will use a finger-stick procedure similar to a blood sugar test. Your total time commitment for all these components is not expected to exceed 2 hours.

**Potential Risks, Discomforts and Inconveniences
This investigation involves two bouts of maximal-intensity aerobic exercise; this will require you to push yourself harder than normal. There is also an increased risk of experiencing a cardiovascular event (e.g. heart attack) during/after a test of maximal exertion. Additionally, you may feel discomfort as the blood sample is being taken, as well as the possibility of** discomfort as researchers are taking measurements during the body composition test, because this requires wearing minimal clothing.

**Potential Benefits
Potential benefits of this study to you include learning your body composition (i.e. bodyfat percentage) and aerobic capacity (i.e. VO2max), as well earning a small amount of extra credit.** **If, at any time during the study, you decide that you cannot keep going, or the investigators determine that it is your best interest to stop testing procedures, you will still be awarded the full benefit of extra credit. The benefits to society include learning more about the relationship between lactate metabolism and health. Recent research has shown that lactate may play a pivotal in health and disease. This could potentially lead to the development of targeted exercise prescriptions as a treatment of diseases, such as cancer. This investigation is viewed as an intermediate, but important, step in developing future protocols which aim to assess metabolic function via less invasive and sub-maximal methods.**

**Study Contact: If you have any questions or concerns about the research, please feel free to contact:**

***(Enter the name of each researcher)* at *(email address)*,** *(phone number if appropriate)*, and *(title such as Student or the faculty/staff members title with the University)* at Colorado Mesa University.

## **COLORADO MESA UNIVERSITY**

## **INFORMED CONSENT TO PARTICIPATE IN A RESEARCH PROJECT**

**TITLE OF PROJECT**

**Assessment of Mitochondrial Function via Blood Lactate Response to Exercise**

**PURPOSE OF THE STUDY**

The purpose of this study is to examine lactate metabolism through stages of exercise resulting in volitional fatigue due to maximum exertion in college aged students using two different maximal exercise protocols (i.e. modified protocol and established protocol).

**PARTICIPATION**

**You can choose whether to participate in this study or not. If you volunteer to be in this study, you may withdraw at any time without consequences of any kind. You may also refuse to answer any questions you do not want to answer and remain in the study. The investigator may withdraw you from this research if circumstances arise which warrant doing so.**

**Participation Requirements**

**To participate in this study, you must be a healthy adult male or female, between the ages of 18 and 30. Additionally, you will be asked to fill out a pre-participation health screening, which will aid in determining your eligibility for this study.**

**Payment for Participation**

**You will not receive any direct payment for participation. A small number of KINE courses will be offering extra credit for participation, however, an alternative means of obtaining that extra credit will be made available for individuals that may not qualify for participation or choose not to volunteer for this investigation.**

**Cost of Participation**

There is no cost to you for participating in this study.

**PROCEDURES**

**All procedures will be conducted in the Monfort Family Human Performance Lab. If you choose to participate in this study, we would ask you to do the following things:**

* **Complete two pre-screening questionnaires to determine if you are eligible for participation**
* **Arrive at the Human Performance Lab at a pre-arranged time for the measurement of your body composition. During this test you will be asked to sit inside the BodPod device for approximately 3-5 minutes. This test will require you to wear minimal clothing (e.g. tight bathing suit)**
* **Perform two (2) graded maximal exercise tests (tests will be scheduled approximately one week apart). Each test will be scheduled between 7 and 10 am and you will be asked to refrain from eating food or drinking caffeinated beverages prior to the test. Each of the two exercise tests will require maximal/near maximal effort and are expected to last approximately 10-15 minutes each, with a total time commitment of approximately 30 minutes per test**
* **During each graded maximal exercise test, you will be asked to give small blood samples which will be generated via a finger-stick procedure**
* **Provide for the research team a dietary log (this will be provided for you) describing your diet, in detail, for the 3-day period prior to each of two (2) graded maximal exercise tests**

**Your total time commitment for everything described above is not expected to exceed two (2) hours.**

**POTENTIAL RISKS, DISCOMFORTS AND INCONVENIENCES**

**This investigation involves two bouts of maximal-intensity aerobic exercise; this will require you to push yourself harder than normal. There is also an increased risk of experiencing a cardiovascular event (e.g. heart attack) during/after a test of maximal exertion.**

A potential risk associated with this study is that you may feel discomfort as researchers are taking measurements including body composition testing and lactate measurements. There are additional risks attributable to maximal exercise testing, including muscle fatigue and shortness of breath. The risk of a fatal event during maximal exercise testing in apparently healthy adults is 0.2 - 0.8 per 10,000 tests and the risk of a non-fatal event is 1.4 per 10,000 tests. The specific risk associated with a cardiovascular event (e.g. heart attack) is similar (<1 in 10,000), however this risk is inversely related to fitness (i.e. the higher your fitness the lower your risk). **The researchers will try to minimize these risks by using standard hygienic technique while performing blood lactate measurements, properly screening volunteers prior to exercise testing, and providing a screening curtain for privacy during body composition testing.**

**POTENTIAL BENEFITS TO SUBJECTS AND / OR TO SOCIETY**

**Potential benefits of this study to you include learning your body composition (i.e. bodyfat percentage) and aerobic capacity (i.e. VO2max), as well earning a small amount of extra credit. If, at any time during the study, you decide that you cannot keep going, or the investigators determine that it is your best interest to stop testing procedures, you will still be awarded the full benefit of extra credit. The benefits to society include learning more about the relationship between lactate metabolism and health. Recent research has shown that lactate may play a pivotal in health and disease. This could potentially lead to the development of targeted exercise prescriptions as a treatment of diseases, such as cancer. This investigation is viewed as an intermediate, but important, step in developing future protocols which aim to assess metabolic function via less invasive and sub-maximal methods.**

**CONFIDENTIALITY**

Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission or as required by law. The only people who will know that you are a research subject and may have access to the records of this research study are: members of the research team and representatives of Colorado Mesa University’s Institutional Review Board, which approves and monitors research studies. These authorized representatives may see your name, but they are bound by rules of confidentiality not to reveal your identity to others.

Any document with your name on it (this document, the Exercise Test Screening Questionnaire and the Physical Activity Readiness Questionnaire) will be kept in a locked file cabinet in the office of the principal investigator. The information contained in these documents is solely for the purpose of determining your eligibility to participate in this study and will not be shared in any way.

All biological data will be stripped of your name and de-identified (i.e. for research purposes, you will be represented by a research number) prior to storage on a password protected computer. The biological data will include heart rate, expired gases (e.g. oxygen and carbon dioxide) body composition, and lactate. This de-identified data will be stored on a password protected computer in the office of the principal investigator. When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity.

**DATA STORAGE AND USE**

**Institutional policy requires research related information be kept in a secure location and retained a minimum of 3 years. Screening questionnaires, the informed consent (i.e. the document you are reading now), and test data will be kept in either a locked file cabinet and/or in password protected computers accessible only by the investigators. Presentation of data will occur in the aggregate only, with no identification of individual participants.**

**The researchers may use or share your de-identified data and will be retained after the study for future research. “De-identified” means that the information collected will not contain your name or other information that can be used to directly identify you. This future research may be similar to this study or it may be different. The researchers will not ask you for any additional consent for these future research studies. Researchers also *may not* inform you of the details of any future research. The researchers may also share your de-identified data with other researchers at Colorado Mesa University or other institutions in the United States or the world.**

**STUDY CONTACTS**

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| **Primary Investigator***Name**Email**Phone**Title* | **Co-Investigator(s)***Name**Email**Phone**Title* |

**RIGHTS OF THE RESEARCH SUBJECTS**

**Your participation in this research is voluntary. If you decide to participate, you may withdraw your consent at any time and discontinue participation without penalty or loss of benefits to which you are otherwise entitled. If you have questions regarding your rights as a research subject or to report a research-related injury, contact the Research Integrity Officer in the Office of Sponsored Programs, Colorado Mesa University, 1100 North Ave., Grand Junction, CO 81501-3122; Telephone: (970) 248-1424. Email:** osp@coloradomesa.edu

**SIGNATURE OF RESEARCH SUBJECT OR LEGAL REPRESENTATIVE**

I understand my participation is voluntary. I understand the procedures and conditions of my participation described above. My questions have been answered to my satisfaction, and I agree to participate in this study. I have been given a copy of this form.

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Printed Name of Participant

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Signature of Participant Date

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Printed Name of Researcher

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Signature of Researcher Date