**Consent to Participate in Biomedical Research**

*Information to Consider About this Research*

**[Title of Research Study]**

Principal Investigator:

Department:

Contact Information:

[include name/contact for faculty advisor if PI is a student]

[If research is externally funded ] This research is funded by:

**What is the purpose of this research?**

Include:

* What do you hope to learn? Start with a simple and condensed background of the study topic. Remember that the language used throughout this form should be at the level of a local student in 6th to 8th grade.
* Describe your intent to publish, if relevant

Example wording:

* You are invited to participate in a research study about…
* By conducting this study we hope to learn…
* The specific purpose of this study is to determine if …..
* The research findings may be published in….

**Why am I being invited to take part in this research?**

[OPTIONAL] **Are there reasons I should not take part in this research?**

Include:

* Describe all criteria that make a person eligible for the study.
* How many participants are being recruited.
* Any reasons a person should not participate in the study (exclusionary criteria). If there are no reasons why, remove the question in the section header.
* Any alternative procedures.

Example wording:

* You are invited to participate in this study because you are a healthy volunteer at least 18 years old with no history of…
* If you volunteer to take part in this study, you will be one of about X people to do so.
* If you are pregnant, or think you may become pregnant during the study, you should not participate in this study*.*

**What will I be asked to do?**

Include:

* The number of visits required and the total estimated time commitment.
* Every procedure of the research, including:
	+ Any screening procedures/pre-study conditions (e.g., a screening questionnaire, stopping over-the-counter drugs or dietary supplements).
	+ Any tests, interventions, or procedures and the purpose of each. If there are multiple visits with different procedures occurring at each visit, consider listing these in a table, separate paragraphs, or bulleted items.
	+ Consider adding a graph or figure to clearly depict the research design and the timing of the procedures.
	+ Describe the types of questions that will be asked during interviews/focus groups
	+ Any audiotaping, videotaping or photography procedures.
	+ Diaries/logs that need to be kept.
	+ Any dietary supplement, drug, device, and the dose that will be given.
	+ Any instructions about what the human subject needs to do before the procedures.

Example wording:

* The research procedures will be conducted at X in room X. You will need to come here X times during the study. Each of those visits will take about X minutes or X hours. The total amount of time you will be asked to volunteer for this study is X over the next X days.
* If you agree to be part of the research study, you will be asked to….
	+ Example text for VO2max test:

The purpose of the VO2max test is to determine your maximum exercise capacity. The time commitment is about 30 to 60 minutes, and you should wear exercise clothes and shoes that allow for free movement during vigorous exercise. You should be rested, well nourished, and hydrated for the test and avoid alcohol, caffeine, and tobacco 3 hours before the test. Avoid significant exertion or exercise the day of testing and report any medication that you are using to the testing staff before the test.

The test will begin with an exercise warm-up period of a few minutes, and then you will either walk/run on a treadmill at different combinations of speed and grade (elevation), or pedal an exercise cycle at progressively harder workloads. The test will continue until you become fatigued and decide to stop, or other symptoms prohibit further exercise. Both leg tiredness and breathlessness are common sensations of the fatigue that you may experience.

During the test, you will wear an apparatus that allows your exhaled air to be analyzed. The apparatus consists of a mouthpiece and breathing valve similar to a scuba diving mouthpiece, with a nose clip to prevent you from breathing through the nose. Alternatively, you may be asked to use a facemask, much like a pilot might wear. Throughout the VO2max test, your heart rate may be monitored either by wearing a chest strap that allows use of a heart rate monitor, or by electrodes that measure electrical activity in your heart (electrocardiogram). Your blood pressure may also be measured during the exercise VO2max test through use of an arm cuff and stethoscope applied to the crook of your arm. You may need to communicate with the lab personnel during the test, either by hand signals or by the use of a perceived exertion chart to indicate how the exercise feels to you.

**What are possible harms or discomforts that I might experience during the research?**

Include:

* The level of risk of the research (e.g., minimal risk means the risks are the same as those encountered in daily life; more than minimal risk means that either the probability of harm or the magnitude of harm is greater than that encountered in daily life).
* Describe all the potential risks and discomforts, and if possible include the relative chance of occurrence and severity:
	+ Physical, psychological, and social risks/discomforts.
	+ Information to be collected could place a participant’s at risk of criminal or civil liability if information is released outside of the research.
	+ Information to be collected could be damaging to a participant’s financial standing, employability, or reputation if information is released outside of the research.
	+ Describe the potential for breach of confidentiality of data.
	+ Risk to pregnancy/fetus*.* If applicable, a statement on how this research may impact reproduction now or in the future.

Example wording:

* To the best of our knowledge, the risk of harm and discomfort from participating in this research study is no more than you would experience in everyday life.
* You must use adequate birth control measures to avoid pregnancy while participating in this study. If you are unwilling to use adequate birth control measures, you should not participate in this study. If pregnancy occurs, there could be risks to the fetus associated with the treatment you are receiving on this study.

Note, the IRB has approved guidelines on the language of risks associated with:

Standard venipuncture: The risks of collecting a blood sample from you include the possibility of requiring more than one attempt to obtain the blood sample, local discomfort (pinch when the needle enters your skin), minor bruising or bleeding at the site (10%), possible temporary lightheadedness, infection (<0.01%), or development of a blood clot (<0.01%). The amount of blood being withdrawn is about [state as X teaspoons or tablespoons] and will not affect your ability to participate in normal daily activities [explain if otherwise]. A trained and experienced individual will perform the technique and your blood will be collected in a hygienic setting with sterile materials and biohazard protection measures to minimize these risks. In the rare case of exposure of your blood or tissue to research personnel, we will analyze your blood for HIV and hepatitis (a positive HIV or hepatitis test will be reported to you).

Peripheral Venous Catheter: The risks of collecting a blood sample from you include the possibility of requiring more than one attempt to obtain the blood sample, local discomfort (pinch when the needle enters your skin), minor bruising or bleeding at the site (10%), or possible temporary lightheadedness, infection (<0.01%), or development of a blood clot (< 0.01%). These risks are slightly increased compared to a standard blood draw.

The amount of blood being withdrawn is about [state as X teaspoons or tablespoons] and will not affect your ability to participate in normal daily activities [explain if otherwise]. A trained and experienced individual will perform the technique and your blood will be collected in a hygienic setting with sterile materials and biohazard protection measures to minimize these risks. In the rare case of exposure of your blood or tissue to research personnel, we will analyze your blood for HIV and hepatitis (a positive HIV or hepatitis test will be reported to you).

DEXA: The risks associated with a DEXA scan include exposure to small amounts of radiation. DEXA scanning utilizes radiation to obtain an image of your body. Everyone receives a small amount of unavoidable radiation from the environment each year. Some of this radiation comes from space and some from naturally-occurring forms of radioactive water and minerals. The DEXA scan technique gives your body the equivalent of about 4 extra days’ worth of this natural radiation. The radiation dose we have discussed is what you will receive from this study only and does not include any exposure you may have received or will receive from other tests. If you are pregnant or trying to get pregnant, you should not participate in a DEXA scan.

VO2 Max tests: The risks associated with participating in this study may include abnormal heart beats, abnormal blood pressure responses, muscle cramps, muscle strain and/or joint injury, delayed muscle soreness (1 to 2 days afterwards), light headedness, fatigue, and in rare instances, heart attack. You must be at LOW RISK for heart disease to take the VO2max test, as assessed by the screening questionnaire. The risk of heart attack during the VO2max test for healthy individuals is close to zero. Several trained staff will supervise the VO2max test. Professional care throughout the entire testing process should provide appropriate precaution against potential problems, and there will be at least one CPR-certified investigator with automated external defibrillator (AED) training present during testing. If at any time during the test you want to stop, you can signal as instructed and the test will be stopped.

[OPTIONAL] **Are there any reasons you might take me out of the research**?

Include:

* Any reasons a participant might be removed from the research.

Example wording:

* There may be reasons we will need to remove you from the study, even if you want to stay in. These include…
* If we learn that the potential benefits of this research do not outweigh the risks of your continued participation, we will [explain what will happen if the person is withdrawn from the study.]
* We may find that you are not or cannot take your supplements as directed and are not coming for your study visits as scheduled so we need to take you out of the study.

**What are possible benefits of this research?**

Include:

* Describe the direct or potential benefits to the participant (excluding compensation).
* Describe why there are no direct benefits to the participant.
* Describe any potential benefits to society as a result of the findings.

Example wording:

* There may be no personal benefit from your participation but the information gained by doing this research may help others in the future.
* By participating in this research, you may benefit by…
* Other people who have [done the research procedures, taken the drug, used the device or biologic] have experienced [explain potential benefits the person may reasonably expect.] By participating in this research study, you may also experience these benefits.
* This research should help us learn more about whether [the experimental procedure, drug, device, biologic] will help…
* One of the benefits of taking the VO2max test is the determination of your maximum exercise capacity. This information may be useful to develop an exercise program individualized to your fitness level. Your VO2max results will also be compared with national norms to let you know your ranking adjusted for gender and age. This study should benefit society by….

**Will I be paid for taking part in the research?**

Include:

* The amount of compensation, if any
* Whether the payment will be made in whole or pro-rated by visit/procedures, etc.
	+ Note, there are reporting requirements for any compensation that exceeds $99

Example wording:

* We [will/ will not] pay you for the time you volunteer while being in this study.
* If compensation exceeds $99: Current University policy requires the collection of Social Security numbers (or Western Colorado University Banner ID numbers) if study compensation is more than $99 for a single study or $599 for participation in multiple studies in a calendar year. Since the compensation for this study is more than $99, you will need to provide your address and Social Security number (or Western Colorado University Banner ID number) when you complete the form for payment.

[OPTIONAL] **What will it cost me to take part in this research?**

Include:

* Explain the potential costs to the participant.

Example wording:

* It will not cost you any money to be part of the research.
* You may need to pay to park near the site of the research.

[OPTIONAL except for studies that are more than minimal risk] **What if I get sick or hurt while participating in this research study?**

Example wording:

In the rare event of an injury during testing, standard emergency procedures will be followed. The exercise testing facility is located within a few minutes of several agencies providing emergency treatment. If you need emergency care while you are at the research site, it will be provided to you. If you get hurt or sick when you are not at the research site, you should call your doctor or call 911 in an emergency. If your illness or injury could be related to the research, tell the doctors or emergency room staff about the research study, the name of the Principal Investigator, and provide a copy of this consent form if possible. Call the principal investigator, [name of Principal Investigator at telephone # where the person will most likely reach you] as soon as you can. He/she needs to know that you are hurt or ill.

There are procedures in place to help attend to your injuries or provide care for you. Costs associated with this care will be billed in the ordinary manner, to you or your insurance company. However, insurance companies, Medicare, and Medicaid may not pay bills that are related to research costs. You should check with your insurance about this and talk to the Principal Investigator if you have concerns.

**How will you keep my private information confidential?**

Include:

* Whether data will be collected anonymously (e.g., the data collected cannot be matched to the identity of the subject) or confidentially.
* The efforts made to protect the confidentiality of the information, such as: names being kept separate from information, replacing names with numbers.
* If the research may involve situations where confidentiality cannot be guaranteed (e.g., duty to report child abuse, misconduct of licensed health care professionals), describe e.g., “Confidentiality will be protected to the full extent of the law.”
* Explain how long data and identifying information will be kept.
* Describe any future use of samples/data -- if the information may be stripped of identifiers and used in future research.
* If you plan to take photos, include statements allowing subjects to indicate whether or not permission is granted.

Example wording:

* For clinical trials, U.S. Health and Human Services requires the following: A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Website will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Website at any time.
* Your information will be combined with information from other people taking part in the study. When we write up the study to share it with other researchers, we will write about the combined information. You will not be identified in any published or presented materials. To ensure that your information is kept confidential, identification numbers but not names will be used on all documents. All data entry and analysis will be conducted with statistical programs using identification. Your files will be stored in Dr. X’s office under lock and key and identifiable information will be deleted after one year.
* All blood and urine samples will be coded with identification numbers only, and samples that remain after all analysis has been completed will be destroyed.
* The FDA may inspect subject files and records from this study.
* With your permission, photos may be taken during the study and used in scientific presentations of the research findings. Your identity will not be revealed when the photos are presented. Please indicate whether or not you agree to having your photo taken for use in scientific presentations (without name identification):
* ⧠ Yes, I grant permission for my photo to be taken and used in scientific presentations.
* ⧠ No, I do not grant permission.

**Whom can I contact if I have a question?**

The people conducting this study will be available to answer any questions concerning this research, now or in the future. You may contact the Principal Investigator at [insert telephone number]. If you have questions about your rights as someone taking part in research, contact the Western Colorado University Human Research Committee member Dr. Gary Van Guilder via email at gvanguilder@western.edu.

**Do I have to participate?**

Include:

* A statement that participation is voluntary.
* Describe that the participant has the right to refuse to participate, or withdraw during the course of the study, without consequences.

Example wording:

* Your participation in this research is completely voluntary. If you choose not to volunteer, there is no penalty or consequence. If you decide to take part in the study you can still decide at any time that you no longer want to participate. You will not lose any benefits or rights you would normally have if you do not participate in the study.

This research project has been approved on \_\_\_\_\_ (date) by the Institutional Review Board (IRB) at Western Colorado University. This approval will expire on [Expiration Date] unless the IRB renews the approval of this research.

**I have decided I want to take part in this research. What should I do now?**

If you have read this form, had the opportunity to ask questions about the research and received satisfactory answers, and want to participate, then sign the consent form and keep a copy for your records.

 \_\_\_\_\_

Participant's Name (PRINT) Signature Date

 \_\_\_\_\_\_\_\_\_\_\_

Witness (PRINT) Signature Date