

Purpose: The IRB Biomedical Subcommittee developed text for the IRB application and consent form to facilitate the review of VO2 max tests of participants who have been rated as low risk for a cardiovascular event through risk factor stratification guidelines from the American College of Sports Medicine's Guidelines for Exercise Testing and Prescription, (8th edition 2010).

Instructions: The text below should be modified as needed to reflect the specific exercise testing protocol for your study and the text language for the consent form should be a part of a more detailed Informed Consent document.

Template responses to some questions from the IRB application

Section IV: Participant Population and Recruitment

4. Explain any inclusion and exclusion criteria for the study:

- Low risk for heart disease when screened by the ACSM criteria

Section VI: Study Procedures

1. Describe research procedures as they relate to human participants.

After obtaining informed consent, study participants will be screened using the Appalachian Screening Questionnaire for Research Involving Exercise to confirm that all participants are rated as low risk before any exercise testing. Participants who are not at low risk will be informed that they cannot participate further in the study.

Prior to the VO2max test, participants will perform an exercise warm-up period of a few minutes. Then participants will be instructed to put on a mask/mouth piece with a breathing valve to collect expired gases. Participants will be instructed to use hand signals to notify researchers about the need to stop the test.

Participants will be asked to 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 the subject becomes fatigued and decides to stop, or other symptoms prohibit further exercise.

During the VO2max test, subject's heart rate may be monitored either through a chest strap attached to a heart rate monitor, or by an electrocardiogram. Blood pressure may also be measured during the VO2max test through use of an arm cuff and stethoscope applied to the arm. Participants may be asked to rate their perceived exertion during the test. After testing, participants will go through an exercise cool-down.

Section VIII: Risks and Benefits of Study

1. Describe the potential risks (e.g., psychological, legal, physical, social harm, loss of confidentiality):

VO2max test risks 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.

2. Assessment of level of risk:

Risks are more than minimal in that either: a) the probability of harm or discomfort anticipated, or b) the magnitude of harm or discomfort anticipated is greater than that encountered in daily life.

3. Describe procedures for protecting against, or minimizing, the potential risks; including (where applicable) how collected data will be monitored to protect the privacy and safety of subjects:

- Only low risk participants will perform tests.
- Participants will receive instructions that they should: 1) wear appropriate exercise clothes and shoes for testing; 2) be well nourished and hydrated prior to testing; 3) avoid alcohol for 12 hours prior to testing and caffeine and tobacco for 3 hours prior to testing; 4) be rested and avoid significant exertion or exercise the day of testing; and 5) report any medication use to the testing staff prior to testing.
- Participants will warm up prior to testing and cool down after testing.
- Standard emergency procedures will be followed in the event of an emergency.
- Masks and mouth pieces are disinfected between participants.
- Participants will be monitored at all times during the VO2max test by at least one technician or investigator who is knowledgeable and trained in two specific areas: 1) administration of graded exercise tests, including ability to conduct pre-test health screenings, and knowledge and recognition of signs and symptoms of cardiovascular disease; 2) procedures for conducting metabolic measures. In addition, the supervising technician and/or investigator will be certified at a level of basic life support (CPR, cardiopulmonary resuscitation) and have automated external defibrillator (AED) training.
- Test termination criteria include any of the following: subject requests to stop, physical or verbal manifestations of fatigue, failure of test equipment.

Template consent language for VO2max test

What will I be asked to do?

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 for 12 hours before the test and 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?

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.

What are possible benefits of this research?

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....

What if I get sick or hurt while participating in this research study?

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

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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.