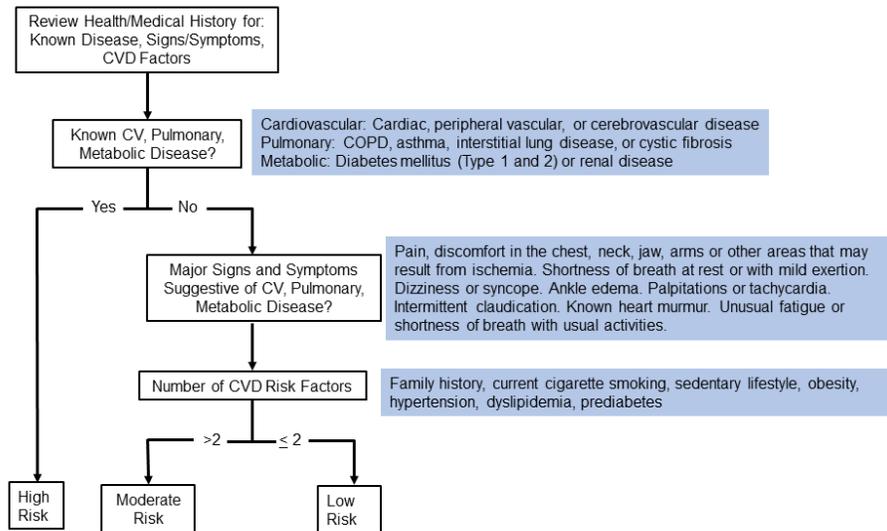


Guidance for Research involving $VO_{2\max}$ and submaximal VO_2 Testing

In Exercise Physiology research, it is often disputed whether some physiological tests should be classified as “minimal risk” or “greater than minimal risk”. This guidance highlights the most controversial of these physiological tests, $VO_{2\max}$ testing, and to a lesser extent submaximal VO_2 testing, and aims to present the factors that would determine the review level and information that should be included in the protocol to help aid in this decision. The definition of $VO_{2\max}$ is maximum rate of oxygen consumption usually measured during incremental exercise (some additional terms used include maximal oxygen uptake, peak oxygen uptake, maximal aerobic capacity, maximal aerobic fitness). Submaximal VO_2 is often defined as aerobic exercise at 85% of $VO_{2\max}$ or lower, but technically could be anything below maximal effort.

OHRP (Office for Human Research Protections) defines minimal risk as “the probability and magnitude of harm or discomfort anticipated in research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests” (45 CFR 46.102(j)). In the case of $VO_{2\max}$ testing, the potential for harm must be identified and estimated for the proposed participants as different populations may have different responses or adverse reactions to exercise testing. For example, an older population with a history of cardiovascular disease may be at greater risk of harm during the test compared to a healthy individual or a trained athlete of any age.

The American College of Sports Medicine (ACSM) has set guidelines for exercising or exercise testing to determine the risk level involved in testing particular individuals/populations (*ACSM’s Guidelines for Exercise Testing and Prescription, Ninth Edition*. Pescatello et. al, 2016). The diagram below demonstrates a hierarchy of circumstances that would predispose an individual for higher risk. *Please note that the table below is from an older edition of ACSM's Guidelines for Exercise Testing & Prescription. Though criteria have been revised for pre-participation health screenings in the 10th edition of the Guidelines, for research purposes, UNM has chosen to keep some of the old guidance to uphold a more conservative standard of practice. Some aspects of the new guidelines (*ACSM’s Guidelines for Exercise Testing and Prescription, Tenth Edition*. Riebe et. al, 2018) are included in this guidance.



Participant Screening:

The ACSM’s Exercise Pre-participation screening questionnaire below can be used to guide the researcher through the screening process.

Assess your potential participant’s health by marking all true statements.

Step 1: Symptoms

Do they experience:

Pain or discomfort in the chest, neck, jaw or arms with exertion, excitement or stress

Unreasonable fatigue or breathlessness at rest or with mild exertion

Dizziness, fainting, blackouts

Shortness of breath in a lying position or while sleeping

Ankle swelling

Unpleasant awareness of forceful, rapid or irregular heart rate

Burning or cramping sensations in the lower legs when walking short distances

Known heart murmur

If you **did** mark any of the statements under the symptoms, they should seek medical clearance before participating in a study that involves exercise or exercise testing.

If you **did not** mark any symptoms, continue to steps 2 and 3.

Step 2: Current Activity

Does your potential participant currently perform planned, structured physical activity of least 30 min at moderate intensity on at least 3 days per week for at least the last 3 months?

Yes No

Continue to step 3.

Step 3: Medical Conditions

Has your potential participant had or do they currently have:

- A heart attack
- Heart surgery, cardiac catheterization, or coronary angioplasty
- Pacemaker/implantable cardiac defibrillator/rhythm disturbance
- Heart valve disease
- Heart Failure
- Heart transplantation
- Congenital heart disease
- Diabetes
- Renal (kidney) disease
- Lung disease (COPD, cystic fibrosis, interstitial lung disease)

Evaluating Steps 2 and 3:

- If you do not mark any of the statements in Step 3, medical clearance is not necessary.
- If you marked “yes” in Step 2 and marked any of the statements in Step 3, they may exercise at light to moderate intensity without medical clearance. Medical clearance is recommended before engaging in vigorous exercise or exercise testing.
- If you marked Step 2 “no” and marked any of the statements in Step 3, medical clearance is recommended before exercising or performing any exercise testing.

Preparing the IRB Protocol:

For studies using $VO_{2\max}$ testing, the following items should be addressed in the protocol:

- the population being studied, specific inclusion/exclusion criteria (health status, age, activity level),
- screening procedures to determine health conditions and risk factors,
- a list of the known risks of $VO_{2\max}$ testing,
- actions that will be taken if known risks of the study occur (i.e. first aid, test termination),
- procedures for medical oversight (who will be present/accessible) during testing.

Keep in mind that UNM IRB reviews studies involving greater than minimal risk procedures (individuals requiring medical clearance) at full board, while non-federally funded studies involving populations at low risk can be considered for minimal risk review (see SOP 205).

VO₂ Submaximal Testing

The use of a submaximal exercise test vs. a maximal test depends largely on the reasons for the test, risk level of the individual, and availability of appropriate equipment and personnel.

Submaximal VO_2 testing requires exercising at one or more submaximal work rates to predict $VO_{2\max}$. It should be noted that submaximal testing is not as accurate as maximal testing.

Recorded measurements during a test includes heart rate, blood pressure, workload, rating of perceived exertion (RPE), and other subjective indices regarding one’s functional response to exercise. The ASCM states that medical professionals be immediately available during the testing of high-risk populations. They also state that appropriately trained non-physicians can

administer maximal or submaximal exercise tests for moderate to low risk populations.

Similar to $VO_{2\text{ max}}$ exercise testing, study submissions to the IRB using submaximal protocols should also include: the population being studied (age, sex, health status), screening procedures to determine health conditions and risk factors, a list of the known risks of submaximal VO_2 testing, actions that will be taken if known risks of the study occur (ie. terminating the test), and the name of the person overseeing the testing (either a physician or clinical exercise physiologist) whom will be present/accessible during testing.