## Guidance for Research involving VO$_{2 \text{ max}}$ 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$_{2 \text{ max}}$ testing, and aims to present the predisposing factors that would determine the review level and information that should be included in the protocol to help aid in this decision.

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" (45 CFR 46.102(i)). In the case of VO$_{2 \text{ max}}$ testing, the potential for harm must be identified and estimated for the proposed participants because different populations may have different responses to the same test. For example, an older population with a history of cardiovascular disease may be at greater risk of harm during the test vs. young healthy trained athletes.

The American College of Sports Medicine has set guidelines for exercise testing and prescription to determine the risk level involved in testing particular individuals/populations (Pescatello, L.S. (2014) *ACSM's guidelines for exercise testing and prescription*. Philadelphia, PA: Wolters Kluwer/Lippincott Williams & Wilkins Health). The diagram below demonstrates a hierarchy of circumstances that would predispose an individual to being at higher risk.
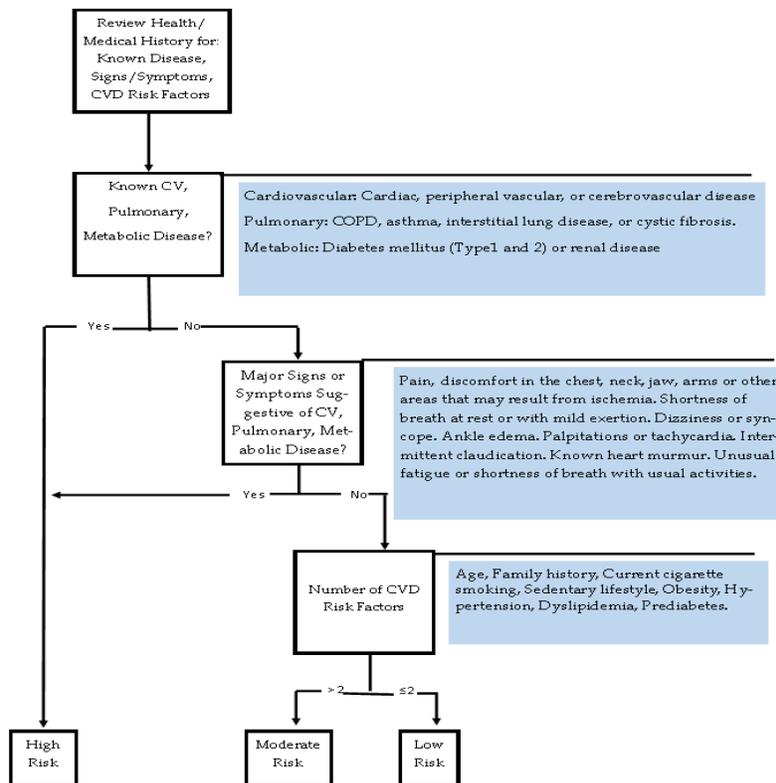
Please note that this table is from the antiquated ACSM's Guidelines for Exercise Testing & Prescription. Though criteria have been revised for pre-participation health screenings, for research purposes, UNM has chosen to keep the old guideline as to uphold a higher standard of practice.

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Participant Screening:

1. The first information to review with the participant is their medical history for known disease, signs/symptoms, and cardiovascular (CV) risk factors. If the individual has known CV, pulmonary, or metabolic disease then he/she is considered high risk during $VO_{2\,max}$ testing.

2. If the individual does not have any known diseases then the next step is to review major signs and symptoms suggestive of CV, pulmonary or metabolic disease; these include pain in the chest, shortness of breath, dizziness, ankle edema, etc. If the participant shows signs of any of these then he/she is at high risk.

3. For participants who answer no to the previous two steps, the last step is to review cardiovascular disease (CVD) risk factors. CVD risk factors include: age, family history, current cigarette smoking, sedentary lifestyle, obesity, hypertension, dyslipidemia, and prediabetes.

Regardless of age, if the participant has more than two of these risk factors he/she is considered to be at moderate risk for $VO_{2\,max}$ testing; if they have ≤ 2 factors they are at low risk. Medical professionals should be present during testing of moderate to high risk populations and accessible for low risk populations.

Preparing the IRB Protocol:

For studies using $VO_{2\,max}$ testing, the following items should be addressed in the protocol:
- the population being studied (age, gender, health status),
- 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 (ie. terminating the test), and
- 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 at full board, while studies involving populations at low risk (≤ 2 CVD risk factors) can be considered for expedited review.

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. It should be noted that submaximal measures are not as accurate as maximal testing measures as the test determines the heart rate response to one or more submaximal work rates and uses the results to predict $VO_{2\,max}$. Additional measures to collect should include heart rate, blood pressure, workload and rating of perceived exertion and other subjective indices as valuable information regarding one's functional response to exercise. ASCM asks that medical professionals be present during the testing of high risk populations and accessible for moderate to low risk populations.

Similar to exercise protocols using $VO_{2\,max}$ testing, protocols performing submaximal tests should also include: the population being studied (age, gender, health status), screening

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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 (ie. terminating the test), and the name of the medical oversight whom will be present/accessible during testing.

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