

Investigator Guidance Series

University of Utah Institutional Review Board

EXERCISE TESTING ON HUMAN SUBJECTS

Adapted from the American College of Sports Medicine 6th Edition [2000].

Description

Low Risk:	Younger Individuals (men <45 yrs; women < 55 yrs) who are asymptomatic and meet no more than one risk factor threshold (see Risk Factor Table below).
Moderate Risk:	Older individuals (men > 45 yrs; women > 55 yrs) or those who meet the threshold for two or more risk factors (see Risk Factor Table below).
High Risk:	Individuals with one or more signs or symptoms listed below in Major Signs or Symptoms Suggestive of Cardiovascular and Pulmonary Disease below or know cardiovascular, pulmonary, or metabolic disease.

Table 1: Risk Factors

Risk Factors	Defining Criteria
Positive	
Family History	Myocardial infarction, coronary revascularization, or sudden death before 55 years of age in father or other male first-degree relative (i.e. brother or son), or before 65 years of age in mother or other female first-degree relative.
Cigarette Smoking	Current cigarette smoker or those who quit within the previous 6 months.
Hypertension	Systolic blood pressure of > 140mmHg or diastolic > 90 mmHg, confirmed by measurements on at least 2 separate occasions, or on antihypertensive medications.
Hypercholesterolemia	Total serum cholesterol of > 200mg/dL or high-density lipoprotein cholesterol of < 35mg/dL, or on lipid-lowering medication. If low-density lipoprotein cholesterol is available, use > 130mg/dL rather than total serum cholesterol of >200mg/dL.
Impaired Fasting Glucose	Fasting blood glucose of > 110mg/dL confirmed by measurements on at least 2 separate occasions.
Obesity	Body Mass Index of > 30kg/m ² or waist girth of > 100cm.
Sedentary Lifestyle	Persons not participating in a regular exercise program or meeting the minimal physical activity recommendations from the U.S. Surgeon General's report.

Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.

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Negative

High Serum

HDL-C > 60mg/dL

Table II: Major Signs or Symptoms Suggestive of Cardiovascular and Pulmonary Disease

- Pain, discomfort (or other anginal equivalents) in chest, neck, jaw, arms or other areas that may be due to ischemia.
- Shortness of breath at rest or with mild exertion
- Dizziness or syncope
- Orthopnea or paroxysmal nocturnal dyspnea
- Ankle edema
- Palpitations or tachycardia
- Intermittent claudication
- Known Heart Murmur
- Unusual Fatigue or shortness of breath with usual activities.

IRB Policy: (A) Physical Examination by M.D. or N.P. Prior to Exercise Testing and (B) Physician Supervision of Exercise Testing.

	Low Risk	Moderate Risk	High Risk
A.			
Moderate Exercise	Not Necessary	Necessary	Necessary
Vigorous Exercise	Not Necessary	Necessary	Necessary
B.			
Moderate Exercise	Not Necessary	Necessary	Necessary
Vigorous Exercise	Not Necessary	Necessary	Necessary

Points to Address

- Protocol Summary:** 1. **Procedures:** Please state whether or not participants will be required to undergo **exercise testing**. If YES, describe when testing will take place, what procedures the testing will entail. **Please note** that a distinction should be made between the procedures for treatment evaluation verses procedures for safety evaluation.
- Consent Document:** 1. **Procedures:** Please state whether or not participants will be required to undergo **exercise testing**. If YES, describe when testing will take place, what procedures the testing will entail, and how long testing will take to complete.
2. **Procedures, Exercise Testing:** Please state whether or not participants will receive the **results** of their exercise test(s).

References & Links

American College of
Sports Medicine

http://www.acsm.org//AM/Template.cfm?Section=Home_Page

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