

## **Clarkson IRB Guidelines on Exercise Safety in Research**

All researchers participating in data collection involving exercise should know the emergency plan in case of injury or adverse event. Clarkson's regulations regarding what to do in case of injury or emergency should be posted in the lab. Researchers supervising cardiovascular exercise at moderate or higher levels be instructed in signs and symptoms of a heart attack (for both men and women) and a poster describing these signs and symptoms should be posted in the lab. (Please contact the IRB if you need a copy of an appropriate poster.) Research involving high cardiovascular risk or vigorous cardiovascular activity should have an Automated External Defibrillator (AED) readily accessible (If your lab includes an AED, please contact the Environmental Health and Safety office (x6640) for additional guidance.)

In any human subjects research, in the case of injury to a subject Clarkson regulations require that you contact Clarkson Campus Safety at 6666 using a campus phone or 268-6666 using your cellphone.

IRB proposals should identify types of risk for any research involving physical activity and describe, in the protocol they submit to IRB, how they are meeting the IRB requirements for managing the appropriate risk:

- Cardiovascular risk: See Appendix A.
- Fall risk: See Appendix B.
- Other physical risk (e.g., musculoskeletal injury): See Appendix C.

## Appendix A: Cardiovascular Risk

For projects with cardiovascular risk, screening should identify cardiovascular risk level for each participant using the procedures below.

Initial cardiovascular screening (for risk/no-risk) can be performed by a research assistant using either of the two methods below.

- Have the subject review the “AHA/ACSM Health/Fitness Facility Pre-participation Screening Questionnaire” (Figure A.1, below). The subject can participate if the guidelines do not indicate that the subject should consult a health care provider or exercise under medical supervision. Questions about prescription medicine, pregnancy, and musculoskeletal conditions limiting physical activity may be addressed through processes detailed in the IRB proposal.

or

- Have the researcher talk the subject through the ACSM logic model for cardiovascular risk stratification (Figure A.2 below). Explain terminology as needed. Subjects can participate if the ACSM logic model indicates Low or Moderate Risk. **The researcher must have sufficient training to answer questions about the criteria.**

After you have determined the level of cardiovascular risk, describe in your IRB protocol how you will manage that risk:

- **Low Risk:** Safe to participate in research up to Vigorous Intensity Activity (Table A.1).
  - *For up to Moderate Intensity cardiovascular activity:* Generic monitoring for symptoms. Research assistants can collect data unsupervised. If unanticipated signs or symptoms arise, exercise should be paused until someone with medical training arrives to assess the individual and clears the subject to continue and if the subject chooses to do so.
  - *For Vigorous Intensity cardiovascular activity:* PI or individual with knowledge and skill adequate to recognize and respond to signs and symptoms is present during and after exercise activities. This person must be able to focus attention on the subject during exercise or any at-risk activities; if data collection requires attention elsewhere then there should be at least two people present during exercise with one person’s primary responsibility to be monitoring the subject for symptoms. If unanticipated signs or symptoms arise, exercise should be paused until the knowledgeable individual clears subject to continue if the subject chooses to do so. We strongly recommend that someone with CPR training be present and Automated External Defibrillator (AED) be available nearby. CPR training is provided through the Environmental Health and Safety department.
- **Low and Moderate Risk:** Safe to participate in research requiring no more than Moderate Intensity cardiovascular exercise (Table A.1 gives some examples; more are available). Generic monitoring for symptoms. Research assistants can collect

data unsupervised. If unanticipated signs or symptoms arise, exercise should be paused until someone with medical training arrives to assess the individual and clears the subject to continue if the subject chooses to do so.

- **High cardiovascular risk:** Subjects at high risk performing moderate level activity or subjects at moderate risk performing vigorous activity: PI or individual with knowledge and skill adequate to recognize and respond to signs and symptoms is present during and after exercise activities. This person must be able to focus attention on the subject during exercise or any at-risk activities; if data collection requires attention elsewhere then there should be at least two people present during exercise with one person's primary responsibility to be monitoring the subject for symptoms. If unanticipated signs or symptoms arise, exercise should be paused until someone with medical training arrives to assess the individual and clears the subject to continue if the subject chooses to do so.

### ***Heart Attacks: Signs and Symptoms to Watch For***

Research involving moderate or vigorous cardiovascular exercise should educate research assistants about the basic signs of cardiovascular distress. If these signs and symptoms are observed, discontinue exercise and call for assistance from someone knowledgeable about signs and symptoms of a heart attack or, if in doubt, call Clarkson Campus Safety at 6666 using a campus phone or 268-6666 using your cellphone.

These warning signs are from the American Heart Association:

- **Chest discomfort.** Most heart attacks involve discomfort in the center of the chest that lasts more than a few minutes, or that goes away and comes back. It can feel like uncomfortable pressure, squeezing, fullness or pain.
- **Discomfort in other areas of the upper body.** Symptoms can include pain or discomfort in one or both arms, the back, neck, jaw or stomach.
- **Shortness of breath** with or without chest discomfort.
- **Other signs** may include breaking out in a cold sweat, nausea or lightheadedness.

Women may experience additional signs of heart attack:

- As with men, women's most common heart attack symptom is chest pain or discomfort. But **women are somewhat more likely than men to experience some of the other common symptoms, particularly shortness of breath, nausea/vomiting and back or jaw pain.**

### ***What is Moderate Exercise vs. Vigorous Exercise?***

Moderate intensity exercise; 40-60% of VO<sub>2</sub>max; 3-6 METs; "an intensity well within the individual's capacity, one which can be comfortably sustained for a prolonged period of time (~45 minutes)."

**Table A.1: CDC/ACSM guidelines (complete list at [http://www.cdc.gov/nccdphp/dnpa/physical/pdf/PA\\_Intensity\\_table\\_2\\_1.pdf](http://www.cdc.gov/nccdphp/dnpa/physical/pdf/PA_Intensity_table_2_1.pdf))**

<p style="text-align: center;"><b>Moderate activity</b> 3.0 to 6.0 METs* (3.5 to 7 kcal/min)</p>	<p style="text-align: center;"><b>Vigorous activity</b> Greater than 6.0 METs (more than 7 kcal/min)</p>
<ul style="list-style-type: none"> <li>• Walking at a moderate or brisk pace of 3 to 4.5 mph on a level surface inside or outside, such as               <ul style="list-style-type: none"> <li>○ walking to class, work, or the store</li> <li>○ walking for pleasure</li> <li>○ walking the dog</li> <li>○ walking as a break from work</li> </ul> </li> <li>• Walking downstairs or down a hill</li> <li>• Racewalking—less than 5 mph</li> <li>• Using crutches</li> <li>• Hiking</li> <li>• Roller skating or in-line skating at a leisurely pace</li> <li>• Bicycling 5 to 9 mph, level terrain, or with few hills</li> <li>• Stationary bicycling—using moderate effort</li> </ul>	<ul style="list-style-type: none"> <li>• Racewalking and aerobic walking—5 mph or faster</li> <li>• Jogging or running</li> <li>• Wheeling your wheelchair</li> <li>• Walking and climbing briskly up a hill</li> <li>• Backpacking</li> <li>• Mountain climbing, rock climbing, rapelling</li> <li>• Roller skating or in-line skating at a brisk pace</li> <li>• Bicycling more than 10 mph or bicycling on steep uphill terrain</li> <li>• Stationary bicycling—using vigorous effort</li> </ul>

## AHA Screening Questionnaire

Assess your health status by marking all *true* statements

### History

You have had:

- a heart attack
- heart surgery
- cardiac catheterization
- coronary angioplasty (PTCA)
- pacemaker/implantable cardiac defibrillator/rhythm disturbance
- heart valve disease
- heart failure
- heart transplantation
- congenital heart disease

*If you marked any of these statements in this section, consult your physician or other appropriate health care provider before engaging in exercise. You may need to use a facility with a medically qualified staff.*

### Symptoms

- You experience chest discomfort with exertion
- You experience unreasonable breathlessness
- You experience dizziness, fainting, or blackouts
- You take heart medications.

### Other health issues

- You have diabetes
- You have asthma or other lung disease
- You have burning or cramping sensation in your lower legs when walking short distances
- You have musculoskeletal problems that limit your physical activity
- You have concerns about the safety of exercise
- You take prescription medications
- You are pregnant

### Cardiovascular risk factors

- You are a man older than 45 years
- You are a woman older than 55 years, have had a hysterectomy, or are postmenopausal
- You smoke, or quit smoking within the previous 6 months
- Your blood pressure is >140/90 mm Hg
- You do not know your blood pressure
- You take blood pressure medication
- Your blood cholesterol level is >200 mg/dL
- You do not know your cholesterol level
- You have a close blood relative who had a heart attack or heart surgery before age 55 (father or brother) or age 65 (mother or sister)
- You are physically inactive (i.e., you get <30 minutes of physical activity on at least 3 days per week)
- You are >20 pounds overweight

*If you marked two or more of the statements in this section you should consult your physician or other appropriate health care provider before engaging in exercise. You might benefit from using a facility with a professionally qualified exercise staff<sup>a</sup> to guide your exercise program.*

- None of the above

*You should be able to exercise safely without consulting your physician or other appropriate health care provider in a self-guided program or almost any facility that meets your exercise program needs.*

<sup>a</sup>Professionally qualified exercise staff refers to appropriately trained individuals who possess academic training, practical and clinical knowledge, skills, and abilities commensurate with the credentials defined in Appendix D.

**FIGURE 2.2.** AHA/ACSM Health/Fitness Facility Preparticipation Screening Questionnaire (Modified from American College of Sports Medicine Position Stand and American Heart Association. Recommendations for cardiovascular screening, staffing, and emergency policies at health/fitness facilities. *Med Sci Sports Exerc.* 1998;30(6):1009–18.)

**ACSM 3-Tier System**

Document presence or absence of the following diseases, signs, symptoms, and risk factors. Terminology for risk factors, signs and symptoms noted in tables 2.2 & 2.3 below. **The researcher using the ACSM 3-Tier System must have the expertise necessary to answer potential subject's questions about the system.**

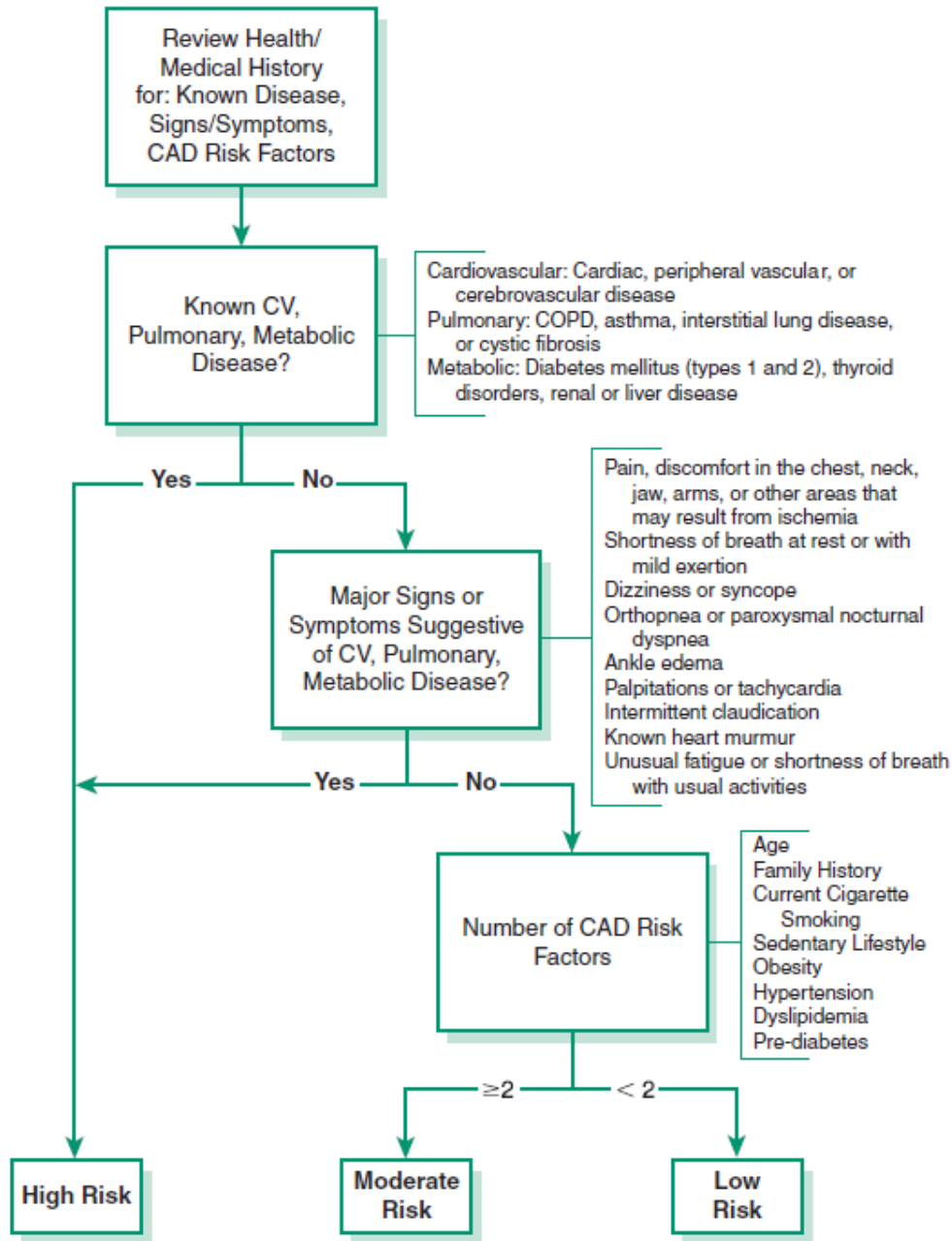


FIGURE 2.3. Logic model for risk stratification.

**TABLE 2.2. MAJOR SIGNS OR SYMPTOMS SUGGESTIVE OF CARDIOVASCULAR, PULMONARY, OR METABOLIC DISEASE<sup>a</sup>**

SIGN OR SYMPTOM	CLARIFICATION/SIGNIFICANCE
Pain, discomfort (or other anginal equivalent) in the chest, neck, jaw, arms, or other areas that may result from ischemia	<p>One of the cardinal manifestations of cardiac disease, in particular coronary artery disease</p> <p>Key features <i>favoring an ischemic origin</i> include:</p> <ul style="list-style-type: none"> <li>• <i>Character</i>: Constricting, squeezing, burning, “heaviness” or “heavy feeling”</li> <li>• <i>Location</i>: Substernal, across midthorax, anteriorly; in one or both arms, shoulders; in neck, cheeks, teeth; in forearms, fingers in interscapular region</li> <li>• <i>Provoking factors</i>: Exercise or exertion, excitement, other forms of stress, cold weather, occurrence after meals</li> </ul> <p>Key features <i>against an ischemic origin</i> include:</p> <ul style="list-style-type: none"> <li>• <i>Character</i>: Dull ache; “knifelike,” sharp, stabbing; “jabs” aggravated by respiration</li> <li>• <i>Location</i>: In left submammary area; in left hemithorax</li> <li>• <i>Provoking factors</i>: After completion of exercise, provoked by a specific body motion</li> </ul>
Shortness of breath at rest or with mild exertion	<p>Dyspnea (defined as an abnormally uncomfortable awareness of breathing) is one of the principal symptoms of cardiac and pulmonary disease. It commonly occurs during strenuous exertion in healthy, well-trained persons and during moderate exertion in healthy, untrained persons. However, it should be regarded as abnormal when it occurs at a level of exertion that is not expected to evoke this symptom in a given individual. Abnormal exertional dyspnea suggests the presence of cardiopulmonary disorders, in particular left ventricular dysfunction or chronic obstructive pulmonary disease.</p>
Dizziness or syncope	<p>Syncope (defined as a loss of consciousness) is most commonly caused by a reduced perfusion of the brain. Dizziness and, in particular, syncope <i>during</i> exercise may result from cardiac disorders that prevent the normal rise (or an actual fall) in cardiac output. Such cardiac disorders are potentially life-threatening and include severe coronary artery disease, hypertrophic cardiomyopathy, aortic stenosis, and malignant ventricular dysrhythmias. Although dizziness or syncope shortly <i>after</i> cessation of exercise should not be ignored, these symptoms may occur even in healthy persons as a result of a reduction in venous return to the heart.</p>
Orthopnea or paroxysmal nocturnal dyspnea	<p>Orthopnea refers to dyspnea occurring at rest in the recumbent position that is relieved promptly by sitting upright or standing. Paroxysmal nocturnal dyspnea refers to dyspnea, beginning usually 2–5 h after the onset of sleep, which may be relieved by sitting on the side of the bed or getting out of bed. Both are symptoms of left ventricular dysfunction. Although nocturnal dyspnea may occur in persons with chronic obstructive pulmonary</p>

(continued)

**TABLE 2.2. MAJOR SIGNS OR SYMPTOMS SUGGESTIVE OF CARDIOVASCULAR, PULMONARY, OR METABOLIC DISEASE<sup>a</sup>**  
(Continued)

SIGN OR SYMPTOM	CLARIFICATION/SIGNIFICANCE
Ankle edema	<p>disease, it differs in that it is usually relieved after the person relieves himself or herself of secretions rather than specifically by sitting up.</p> <p>Bilateral ankle edema that is most evident at night is a characteristic sign of heart failure or bilateral chronic venous insufficiency. Unilateral edema of a limb often results from venous thrombosis or lymphatic blockage in the limb. Generalized edema (known as anasarca) occurs in persons with the nephrotic syndrome, severe heart failure, or hepatic cirrhosis.</p>
Palpitations or tachycardia	<p>Palpitations (defined as an unpleasant awareness of the forceful or rapid beating of the heart) may be induced by various disorders of cardiac rhythm. These include tachycardia, bradycardia of sudden onset, ectopic beats, compensatory pauses, and accentuated stroke volume resulting from valvular regurgitation. Palpitations also often result from anxiety states and high cardiac output (or hyperkinetic) states, such as anemia, fever, thyrotoxicosis, arteriovenous fistula, and the so-called idiopathic hyperkinetic heart syndrome.</p>
Intermittent claudication	<p>Intermittent claudication refers to the pain that occurs in a muscle with an inadequate blood supply (usually as a result of atherosclerosis) that is stressed by exercise. The pain does not occur with standing or sitting, is reproducible from day to day, is more severe when walking upstairs or up a hill, and is often described as a cramp, which disappears within 1–2 min after stopping exercise. Coronary artery disease is more prevalent in persons with intermittent claudication. Patients with diabetes are at increased risk for this condition.</p>
Known heart murmur	<p>Although some may be innocent, heart murmurs may indicate valvular or other cardiovascular disease. From an exercise safety standpoint, it is especially important to exclude hypertrophic cardiomyopathy and aortic stenosis as underlying causes because these are among the more common causes of exertion-related sudden cardiac death.</p>
Unusual fatigue or shortness of breath with usual activities	<p>Although there may be benign origins for these symptoms, they also may signal the onset of, or change in the status of cardiovascular, pulmonary, or metabolic disease.</p>

<sup>a</sup>These signs or symptoms must be interpreted within the clinical context in which they appear because they are not all specific for cardiovascular, pulmonary, or metabolic disease.

Modified from Gordon SMBS. Health appraisal in the non-medical setting. In: Durstine JL, King AC, Painter PL. *ACSM's resource manual for guidelines for exercise testing and prescription*. Philadelphia (PA): Lea & Febiger; 1993. p. 219–28.

**TABLE 2.3. ATHEROSCLEROTIC CARDIOVASCULAR DISEASE (CVD) RISK FACTOR THRESHOLDS FOR USE WITH ACSM RISK STRATIFICATION**

POSITIVE RISK FACTORS	DEFINING CRITERIA
Age	Men $\geq 45$ yr; Women $\geq 55$ yr
Family history	Myocardial infarction, coronary revascularization, or sudden death before 55 yr of age in father or other male first-degree relative, or before 65 yr of age in mother or other female first-degree relative
Cigarette smoking	Current cigarette smoker or those who quit within the previous 6 months or exposure to environmental tobacco smoke
Sedentary lifestyle	Not participating in at least 30 min of moderate intensity (40%–60% $\dot{V}O_2R$ ) physical activity on at least three days of the week for at least three months (20,23)
Obesity <sup>a</sup>	Body mass index $\geq 30$ kg·m <sup>2</sup> or waist girth $>102$ cm (40 inches) for men and $>88$ cm (35 inches) for women (2)
Hypertension	Systolic blood pressure $\geq 140$ mm Hg and/or diastolic $\geq 90$ mm Hg, confirmed by measurements on at least two separate occasions, or on antihypertensive medication (10)
Dyslipidemia	Low-density lipoprotein (LDL-C) cholesterol $\geq 130$ mg·dL <sup>-1</sup> (3.37 mmol·L <sup>-1</sup> ) or high-density lipoprotein (HDL-C) cholesterol $<40$ mg·dL <sup>-1</sup> (1.04 mmol·L <sup>-1</sup> ) or on lipid-lowering medication. If total serum cholesterol is all that is available use $\geq 200$ mg·dL <sup>-1</sup> (5.18 mmol·L <sup>-1</sup> ) (3)
Prediabetes	Impaired fasting glucose (IFG) = fasting plasma glucose $\geq 100$ mg·dL <sup>-1</sup> (5.50 mmol·L <sup>-1</sup> ) but $<126$ mg·dL <sup>-1</sup> (6.93 mmol·L <sup>-1</sup> ) or impaired glucose tolerance (IGT) = 2-hour values in oral glucose tolerance test (OGTT) $\geq 140$ mg·dL <sup>-1</sup> (7.70 mmol·L <sup>-1</sup> ) but $<200$ mg·dL <sup>-1</sup> (11.00 mmol·L <sup>-1</sup> ) confirmed by measurements on at least two separate occasions (8)
NEGATIVE RISK FACTOR	DEFINING CRITERIA
High-serum HDL cholesterol <sup>†</sup>	$\geq 60$ mg·dL <sup>-1</sup> (1.55 mmol·L <sup>-1</sup> )

Note: It is common to sum risk factors in making clinical judgments. If HDL is high, subtract one risk factor from the sum of positive risk factors, because high HDL decreases CVD risk.

<sup>a</sup>Professional opinions vary regarding the most appropriate markers and thresholds for obesity; therefore, allied health professionals should use clinical judgment when evaluating this risk factor.

### **Appendix B: Fall Risk**

For projects with fall risk, screening should quantify the degree of fall risk for each participant. The two-part fall screening can be performed by the primary researcher or research assistant:

1. Has person fallen in the past 6 months? If "yes," then the person is positive for fall risk. If "no," complete the second part.
2. Perform a "Timed Up and Go" test: if the time is greater than 14 seconds, then the person is a fall risk. (General test procedures available at <http://www.nyc.gov/html/doh/downloads/pdf/win/tug-test.pdf>.)

Follow the procedures listed below for the relevant level of fall risk:

#### ***No Fall Risk***

- Person monitoring for signs & symptoms of balance problems does not need special training in fall risk. Research assistants can collect data unsupervised.

#### ***Possible Fall Risk***

- An individual with knowledge and skill adequate to recognize and respond to balance dysfunctions is with the subject during data collection and any time when a fall risk is present during the research process. There needs to be a plan in case of fall. This person must be able to focus attention on the subject during fall risk activities.

*or*

- Procedures are in place to eliminate chance of fall even with loss of balance (e.g., harness support). All researchers collecting data must be trained in adequate safety protocols to minimize chance of fall during all stages of subject participation. There needs to be a plan in case of fall.

Also, in your protocol, indicate that in the case of injury you will call Clarkson Campus Safety at 6666 using a campus phone or 268-6666 using your cellphone.

### Appendix C: Other Physical Risk

There is no single screening tool appropriate to all situations. Your proposal must include an appropriate screening tool and risk management plan. You can draw on the guidelines listed below as you draft your proposal.

In your protocol, indicate that in the case of injury you will call Clarkson Campus Safety at 6666 using a campus phone or 268-6666 using your cellphone.

#### ***Low Risk Of Injury, Possible Injury Would Be Minor***

Individual monitoring for signs and symptoms of musculoskeletal problems does not need special training in injury assessment. Research assistants can collect data unsupervised.

#### ***Moderate Risk Of Injury Or Injury Could Be Moderately Severe***

Researchers screening and interacting with subjects must have adequate knowledge and skill to recognize and respond to signs and symptoms present during or after exercise activities. There needs to be a plan in case of injury.