

# Guidelines for protocols involving physical activity and exercise

The risks to subjects from physical activity and exercise relate very closely to the intensity of the exercise and the health of the individuals. Materials have been prepared to help IRB members and researchers better understand those risks. All IRB applications need to provide sufficient information so IRB members can determine risk and understand precautions taken by researchers to protect subjects. The following information should be included in the application:

- How the researcher will determine coronary artery disease risk level of subjects performing aerobic or strength exercise.
- How researcher will monitor intensity of exercise.
- Signs (e.g., blood pressure > ?) that will prevent subject from beginning exercise or will stop the activity once it has begun.
- Training/experience of researcher to execute protocol safely.

Please consider reviewing Things to Consider, Sample Language for Consent Forms, and appropriate Decision Trees before submitting the IRB application.

## THINGS TO CONSIDER

**General information.** Initiating a sport or physical activity program or challenging an individual to assess his or her physiological ability or fitness level can put the individual at risk. The paradox of exercise is that: “Habitual physical activity reduces coronary heart disease events, but vigorous activity can also acutely and transiently increase the risk of sudden cardiac death and acute myocardial infarction in susceptible persons” (Thompson et al., 2007, p. 886). While there are risks associated with regular physical activity, risks associated with a sedentary lifestyle far exceed them (Cress et al., 2004).

“The absolute risk of an exercise-related cardiovascular event varies with the prevalence of diagnosed or occult cardiac disease in the study population but appears to be extremely low in ostensibly healthy subjects” (Thompson et al., 2007, p. 888).

“Vigorous exercise increases the risk of a cardiovascular event during or soon after exertion in both young subjects with inherited cardiovascular disease and adults with occult or diagnosed CHD. Nevertheless, no evidence suggests that the risks of physical activity outweigh the benefits for healthy subjects” (Thompson et al., 2007, p. 890).

“In general, the risk of vigorous physical activity is an interaction of the exercise per se and the individual’s physical fitness because identical physical tasks evoke lower cardiac demands in physically fit subjects than in unfit persons” (Thompson et al., 2007, p. 891).

**Emergency plan.** The emergency plan for any testing situation must be in place and clear to the researcher(s) prior to any physical testing of a subject. The requirements of the emergency plan (e.g., telephone available, AED device, researcher with current CPR) will be determined by the facility and the type of research being conducted. Explain the emergency plan in the IRB application.

**Training and experience of researcher and/or assistants.** The risk to the research subjects performing physical activity is related to the person who screens the subjects and/or conducts the physical testing and physical training. The experience and training of the individuals who are conducting research with the specific subject group(s) must be clearly explained in the IRB application as well as in the informed consent form.

**Physically active individuals.** If the maximum level of testing and/or training is at or below the level of an individual’s regular activity level, the risk of participation is lower than for activity that challenges a person at above his or her normal level.

**Ability to self monitor.** Subjects must have the cognitive ability to self monitor accurately in the following situations: (1) RPE is used to monitor intensity; (2) subjects are expected to recognize their unusual physiological responses to exercise; and (3) subjects must monitor their intensity subjectively. Those inexperienced with activity challenges, and those with cognitive decline, mental retardation, or other reasons for a lowered ability to self monitor must be supervised closely by the researcher.

**Communication issues.** The researcher and subject must know how they will communicate prior to testing when communication during testing will be difficult (e.g., when subject wears a mask covering the mouth during VO<sub>2</sub> testing, or while underwater during underwater weighing). For example it might be useful to practice procedures (e.g., hand signals) where either the subject or the researcher terminates the test.

**Language on IRB application and informed consent form.** Write in language that the target reader will understand. Do not use jargon, technical terms or language at a level that is beyond the understanding of the reader. The IRB and participant must know what to expect and do not need to be impressed with the expertise of researcher or the in depth review of literature related to the topic.

**Privacy of results.** This is a concern when the participant can be observed by individuals other than the researcher or assistants. If group testing is involved, the researcher must be aware that confidentiality of scores or performance may be compromised. If the performance can be observed by others, this must be included in the informed consent form even though the actual scores or measured results will be kept confidential.

**Encouragement vs intimidation.** The researcher must consider the balance between encouraging and intimidating subjects into continuing. For example, loud encouragement is often used to get a good maximum performance (VO<sub>2</sub> max) for cardiovascular testing, or good maximal voluntary contraction (MVC) commonly needed with EMG testing. The subjects must be able to terminate the test at any time and know there will be no reprisal. Reviewing what the subject may experience would be prudent to do prior to initiating the exercise in these circumstances and included in the consent form. At all times the participants must be treated with respect, not as objects of research.

**Older adults.** Although guidelines for working with older adults are the same as for younger adults, older adults are generally at greater risk during exercise because they have an increased risk of having metabolic (diabetes) and cardiovascular (CAD, hypertension) disease, skeletal risk (arthritis, osteoporosis), and chance of falling (balance, quickness). The cognitive ability to give consent may be compromised through dementia or illness which requires consent by a legal guardian. Someone with a health power of attorney may not be able to give consent for his or her ward to participate in research.

**Resting levels.** Resting blood pressure and heart rate must be monitored prior to any cardiovascular or strength activity in individuals who are identified as moderate or high coronary artery disease (CAD) risk. They will not be permitted to participate if these levels are above 140/90 mmHg or 90 beats/min, respectively unless their physician has provided other guidelines.

**Exercise blood pressure and heart rate.** During aerobic and muscular strength/endurance/power exercise, it is incumbent on the researcher to know that people who are at risk are responding normally to the exercise challenge. During the first and possibly subsequent sessions, exercise blood pressure and heart rate must be monitored regularly for the following: (a) subjects who are at high CAD risk during all activity, and (b) subjects who are at moderate CAD risk during vigorous/high intensity activity (Howley & Franks, 2007).

**Balance/mobility.** Risk is determined mainly by the individual population (e.g., older adults with balance deficits), level of challenge including an awareness of sensory integration concerns (shutting eyes, uneven surface, moving head, etc.), and instructor's experience in leading the challenge and sensitivity to risks for the particular population. The instructor's experience in this regard should be included in the IRB application.

**Use of Rating of Perceived Exertion scale (RPE).** Participants must be trained in the use of an RPE scale before it is used during training or testing. They must have the cognitive ability to relate their feelings to the scale.

**Informed consent.** Subjects in research must know what to expect. It is incumbent on the researcher to clearly describe all protocols in language understandable to the subject. The possible risks of exercise (e.g., falling, experiencing a cardiac event, or even death) can sound daunting to novice exercisers. Describing the low likelihood of an event (e.g., incidence of injury in similar testing) can mitigate subject anxiety. It might be helpful to develop a video of the procedures using age-matched subjects in order to show the subject what to expect.

**General safety.** Subjects' safety must be a concern throughout the exercise or testing experience. This includes subjects climbing onto equipment, picking up weights, getting off equipment, etc.

**Medical clearance.** Some subjects will need their physician's consent before participating in the study. The medical clearance form given to the physician should describe in detail what the subjects will be expected to do. The physician should make clear if the patient's participation is endorsed with or without any conditions. Submit the medical clearance form and any other material given to the physician with the IRB application (Jones & Rose, 2005).

## REFERENCES

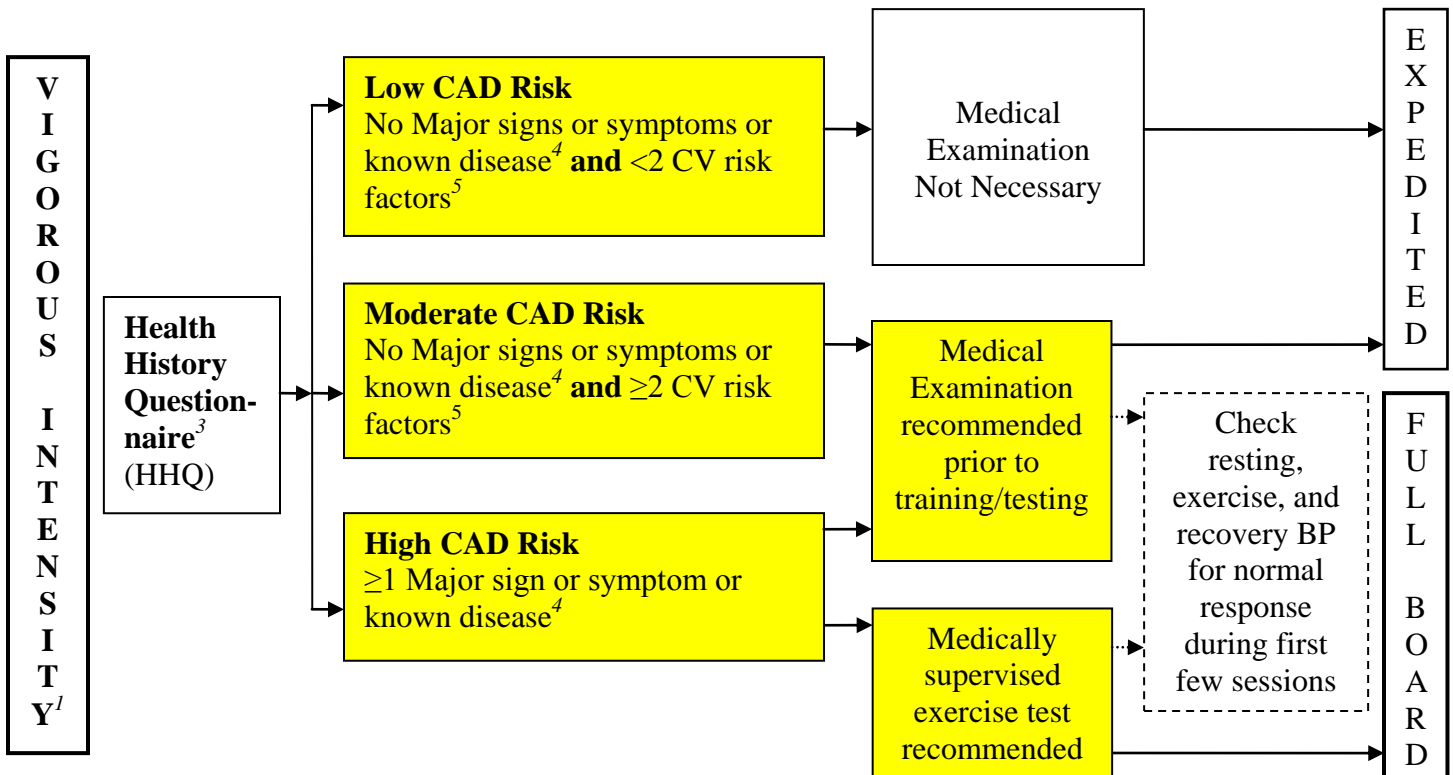
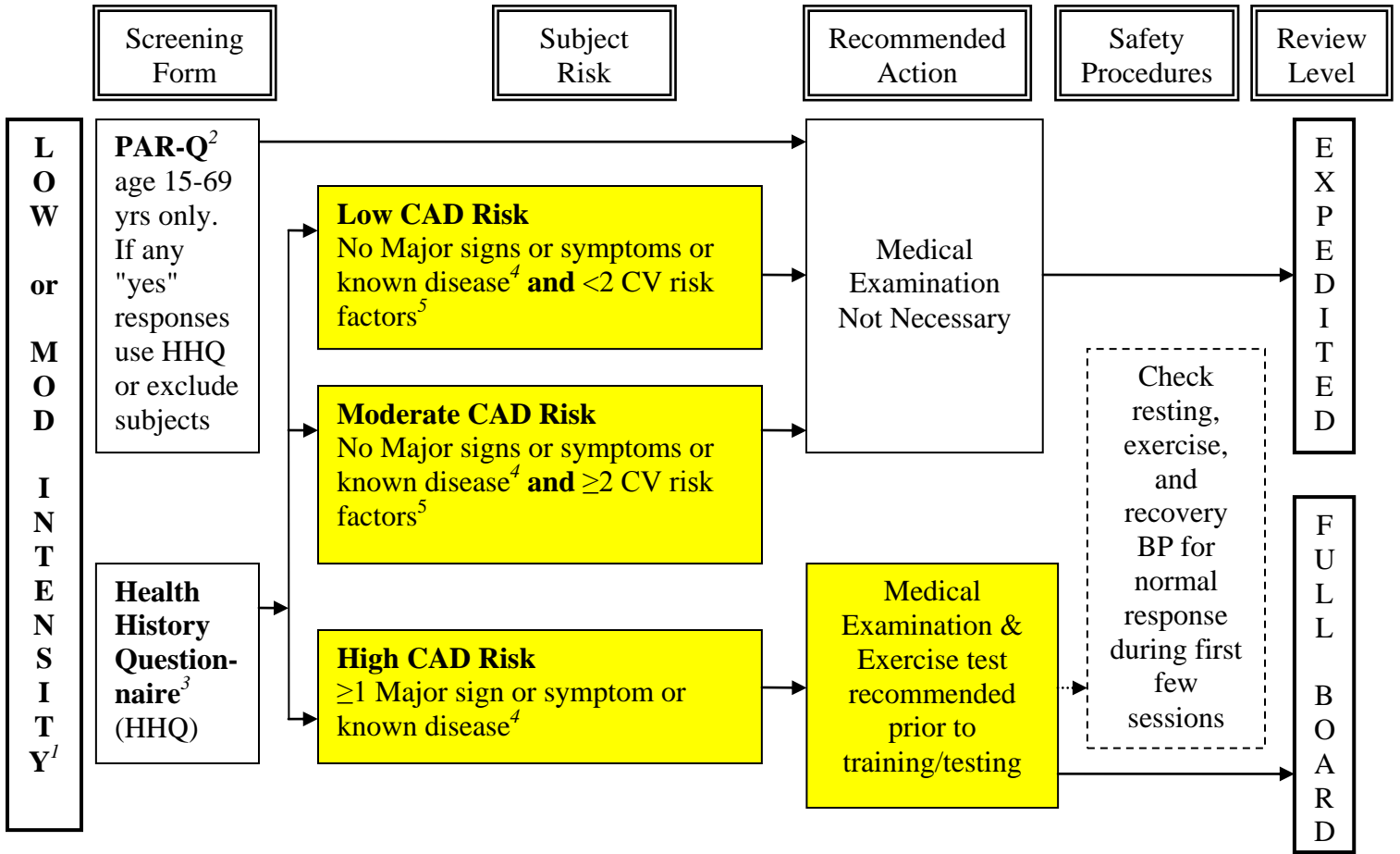
- Cress, M.E., Buchner, D.M., Prohaska, T., Rimmer, J., Brown, M., Macera, C., et al. (2004). Physical activity programs and behavior counseling in older adult populations. *Medicine and Science in Sports and Exercise*, 36(11), 1997-2003.
- Howley, E.T., & Franks, B. D. (2007). *Fitness professional's handbook* (5<sup>th</sup> ed.). Champaign, IL: Human Kinetics.
- Jones, C.J., & Rose, D.J. (2005). *Physical activity instruction of older adults*. Champaign, IL: Human Kinetics.
- Thompson, P., Franklin, B.A., Balady, G.J., Blair, S.N., Corrado, D., Estes III, N.A.M. et al. (2007). ACSM position stand: Exercise and acute cardiovascular events- Placing the risks into perspective. *Medicine and Science in Sports & Exercise*, 39(5), 886-897.

## DECISION TREES FOR DETERMINING RISK AND REVIEW LEVEL

There are five decision trees that cover exercise protocols. One for children and youth (<18 years old), and four for adults over 18 years of age with separate trees for: aerobic, strength or resistance, flexibility, and balance or mobility exercise. Each of the decision trees is organized according to the following topic areas: exercise intensity, health screening, subject risk level, recommended action, and level of IRB review. For each mode of exercise, the intensity of exercise is the first key decision to be made, followed by the health risk of the exerciser. By moving from left to right, determine the level of exercise intensity and the required subject screening. With information gathered from the appropriate screening form, determine subject risk which will lead to the recommended action regarding physician involvement and safety procedures. This stepwise progression leads ultimately to the recommended IRB review level: expedited or full board.

Each decision tree focuses on a specific type of exercise. If subjects will perform more than one type of exercise, then each relevant decision tree will need to be consulted to determine the best course of action.

## Aerobic Exercise Decision Tree for Adults (18 years and older)



The posted Aerobic Decision Tree is a modified version of the tree published in a paper by Pamela Macfarlane and Marilyn Looney, "Expediting' the Institutional Review Board Process for Exercise Science Protocols," *Research Quarterly for Exercise and Sport*, 82, 129-134.

## Abbreviations and Notes for the Aerobic Exercise Decision Tree for Adults

Abbreviations			
ACSM	American College of Sports Medicine	HR	Heart rate
BP	Blood Pressure	HRR	Heart rate reserve
CAD	Coronary Artery Disease	LDL	Low density lipoprotein
CV	Cardiovascular	RPE	Rating of perceived exertion
HDL	High density lipoprotein	VO <sub>2</sub> max	Maximal oxygen uptake
HHQ	Health history questionnaire		

### <sup>1</sup> Exercise intensity for Aerobic Exercise.

The following are guidelines. A key issue relates to the individual and how that individual responds to an exercise challenge. *Ref: Modified from Centers for Disease Control and Prevention (2008)*

Test/activity	Light	Moderate	Vigorous
% HR max	35-54	55-69	>70
% HRR or % VO <sub>2</sub> max	20-39	40-59	>60
MET level	<3	3 to <6	≥6
Perception of heart rate and breathing	Minimal increases	Noticeable increases	Substantial increases
Talk test	Could sing	Comfortable conversation	Winded, too out of breath to share a conversation
Borg's 20 point RPE (Borg, 1998)	<12	12-14 "somewhat hard"	15-20 ≥ "heavy (hard)"
Borg's CR-10 Perceived exertion (Borg, 1998)	0-3 "easy"	4-6 "somewhat strong" to "strong (heavy)"	7-10 ≥ "very strong"
Walking	Slow	Brisk	Race walking
Golf	Power cart	Pull cart	Carry clubs
Swimming	Treading water	Recreational swim	Fast lap swim
Gardening	Pruning	Power mower	Hand mower
Housework	Dusting & vacuuming	Scrubbing floors, washing windows	Moving furniture

### <sup>2</sup> PAR-Q

*Ref: Canadian Society for Exercise Physiology (2002)*

The PAR-Q use is restricted to the format available from <http://uwfitness.uwaterloo.ca/PDF/par-q.pdf>  
Use the standard form when screening subjects.

According to Howley and Franks (2007), question 5 on the PAR-Q: "Do you have a bone or joint problem (for example, back, knee, hip) that could be made worse by a change in your physical activity?" elicits a large number of false positives.

In some instances the PAR-Q may elicit insufficient information to assess risk associated with the protocol (e.g., a participant with an implanted electronic device must not be tested using bioelectric impedance) or a targeted population (e.g., participants who have asthma are at greater risk during vigorous activity). In these instances use the Health History Questionnaire<sup>3</sup>.

### <sup>3</sup> Health History Questionnaire (HHQ)

*Ref: ACSM (2014)*

Refer to ACSM (2014, p. 25) for an example of a health history questionnaire. This questionnaire is used to determine known disease, signs and symptoms, and coronary artery disease risk (CAD) factors. The health history questionnaire must also include protocol-specific questions to identify additional risks associated with the protocol (e.g., a participant with an implanted electronic device must not be tested using bioelectric impedance) or a targeted population (e.g., older adults may be at greater risk for falling in a weight bearing activity).

### <sup>4</sup> Major Signs and Symptoms or Known Disease or Condition

1. Major signs or symptoms suggestive of CV, Pulmonary or Metabolic Disease:
  - a. Pain, discomfort in the chest, neck, jaw, arms or other areas that may result from ischemia.
  - b. Shortness of breath at rest or with mild exertion.
  - c. Dizziness or fainting
  - d. Difficulty breathing when lying down or during sleep
  - e. Swelling in one or both ankles
  - f. Heart rate irregularities
  - g. Acute cramp like pain in muscles when exercising that subsides when exercise is stopped
  - h. Known heart murmur
  - i. Unusual fatigue or shortness of breath with usual activities
2. Known Disease or Condition
  - a. Cardiovascular: cardiac, peripheral vascular, or cerebrovascular disease
  - b. Pulmonary: COPD, asthma, interstitial lung disease, or cystic fibrosis
  - c. Metabolic: Diabetes mellitus (Types 1 and 2) or renal disease
  - d. Thyroid or Liver disease
  - e. Other considerations (e.g., pregnancy)

*Ref: ACSM (2008, 2010, 2014)*

### <sup>5</sup> Coronary Artery Disease Risk Factors

*Ref: ACSM (2010, 2014)*

1. Age: men  $\geq 45$  years, women  $\geq 55$  years.
2. Family History of heart disease: Sudden death, heart attack or coronary revascularization surgery in one or more close relative. Father or brother younger than 55 yr; mother or sister younger than 65 yr.
3. Cigarette Smoking: Current smoker or having quit within the last 6 months, or exposed to environmental tobacco smoke.
4. Sedentary lifestyle: Not participating in at least 30min of moderate intensity physical activity on at least three days of the week for at least three months.
5. Obesity: BMI  $\geq 30$  kg/m<sup>2</sup> or waist girth  $> 102$  cm (40 inches) for men and  $> 88$  cm (35 inches) for women. Allied health professionals ought to use clinical judgment when evaluating this risk factor as thresholds for obesity vary. Individuals with large muscle mass may have a high BMI and waist circumference in the absence of obesity.
6. \*High Blood Pressure: On medication for blood pressure OR blood pressure at or above 140/90 mmHg (either number high) on  $\geq 2$  occasions.
7. \*Blood lipids: On medication for lowering blood lipids OR one of the following: LDL (bad) cholesterol over  $\geq 130$  mg/dl; or HDL (good) cholesterol  $< 40$  mg/dl. If only total cholesterol level available: use  $\geq 200$ mg/dl;
8. \*Prediabetes. Impaired fasting glucose  $\geq 100$  mg/dl but  $< 126$  mg/dl or impaired glucose tolerance test  $\geq 140$  mg/dl but  $< 200$  mg/dl on  $\geq 2$  occasions. Note: glucose  $> 126$  mg/dl represents a *symptom* of metabolic disease, not a risk factor.



**Notes:**

1. \*Blood pressure, blood lipids and glucose should be confirmed on  $\geq 2$  occasions.
2. If HDL cholesterol  $\geq 60$  mg/dl, subtract one risk factor from total.
3. If information for a risk factor is not available it should be counted as a risk except for prediabetes. Count missing glucose as a risk factor for men and women  $\geq 45$  years w/ BMI  $\geq 25$  kg/m<sup>2</sup>; and for men and women under 45 who have a BMI  $\geq 25$  kg/m<sup>2</sup> and have one or more additional risk factors for prediabetes (e.g. excess abdominal fat, inactivity, family history of diabetes mellitus).
4. Missing values are not considered a risk factor if the person has had an assessment of the risk factor (e.g., blood pressure, cholesterol, etc.), does not know his or her numbers, but was told they were acceptable in the past year.

Major signs and symptoms and CAD risk factors are adapted, with permission, from American College of Sports Medicine. *ACSM's Guidelines for Exercise Testing and Prescription* (8<sup>th</sup> ed.). Philadelphia: Lippincott Williams & Wilkins, 2010, pp. 23, 26-28.

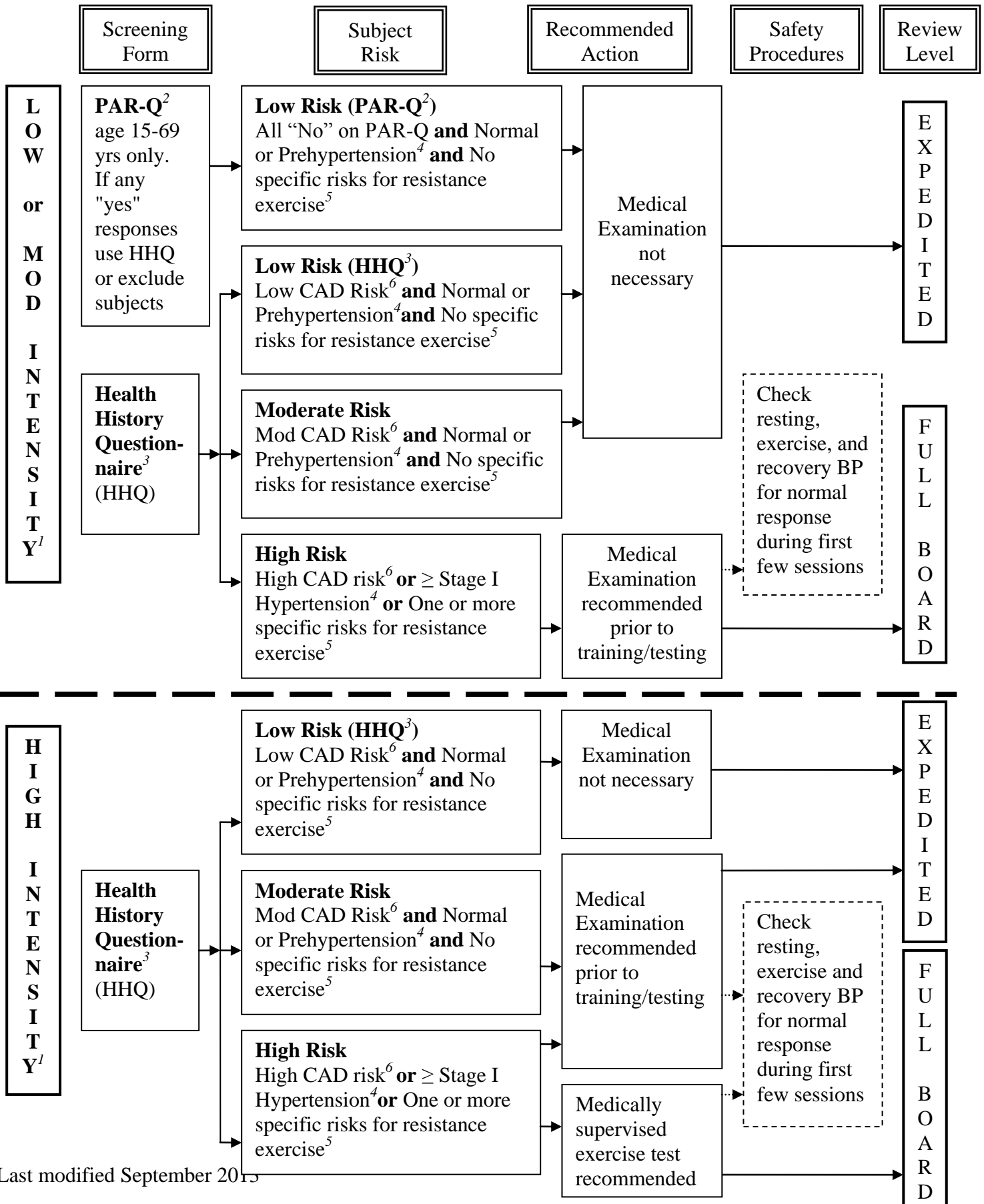
**The Exercise Decision Trees serve as guidelines for the Institutional Review Board. If a researcher wishes to deviate from the guidelines s/he must provide justification for any modifications.**

## REFERENCES FOR AEROBIC EXERCISE DECISION TREE FOR ADULTS

- American College of Sports Medicine. (2014). *ACSM's guidelines for exercise testing and prescription* (9<sup>th</sup> ed.). Philadelphia: Lippincott Williams & Wilkins.
- American College of Sports Medicine. (2010). *ACSM's guidelines for exercise testing and prescription* (8<sup>th</sup> ed.). Philadelphia: Lippincott Williams & Wilkins.
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- Howley, E.T., & Franks, B.D. (2007). *Fitness professional's handbook* (5<sup>th</sup> ed.). Champaign, IL: Human Kinetics.

# Strength/Resistance Exercise Decision Tree for Adults (18 years and older)

## Traditional Strength Testing and Training Protocols



## <sup>1</sup> Description of Intensity for Muscular Strength, Endurance and Power

Moderate Intensity	High Intensity
>10 Reps to moderate fatigue (can still do 3 reps at end point)	Set of Reps (using any resistance) until subject can do no more reps
RPE 12-16 on Borg's 20 point RPE Scale (Ref: Borg, 1998)	RPE $\geq 17$ on Borg's 20 point scale (Ref: Borg, 1998)
RPE 4-6 on Borg's CR-10 Scale (Ref: Borg, 1998)	RPE $\geq 7$ on Borg's CR-10 scale (Ref: Borg, 1998)
50% to 70% Maximal voluntary isometric contraction	> 70% Maximal voluntary isometric contraction
40-60% 1RM	$\geq 80\%$ 1 RM
	Sustained Isometric contraction with elevated BP

Moderate and high risk subjects must not be allowed to perform the Valsalva maneuver, increase BP by sustained gripping, or sustained upper body static contractions. It is safer to use machines versus free weights for persons who have joint, bone, neuropathy or neurological issues.

*Note:* The Williams et al. (2007) resource includes guidelines specifically for resistance training in individuals with cardiovascular disease. See the references below for apparently healthy adults, older adults, and cardiac patients.

*Ref: ACSM (2010, 2014); Cress et al. (2004); Ratamess (2009); Williams et al. (2007)*

## <sup>2</sup> PAR-Q *Ref: Canadian Society for Exercise Physiology (2002)*

The PAR-Q use is restricted to the format available from <http://uwfitness.uwaterloo.ca/PDF/par-q.pdf>

Use the standard form when screening subjects.

According to Howley and Franks (2007), question 5 on the PAR-Q: “Do you have a bone or joint problem (for example, back, knee, hip) that could be made worse by a change in your physical activity?” elicits a large number of false positives.

In some instances the PAR-Q may elicit insufficient information to assess risk associated with the protocol (e.g., a participant with an implanted electronic device must not be tested using bioelectric impedance) or a targeted population (e.g., participants who have asthma are at greater risk during vigorous activity). In these instances use the Health History Questionnaire<sup>3</sup>.

## <sup>3</sup> Health History Questionnaire (HHQ)

Refer to ACSM (2010, p. 21) for an example of a health history questionnaire. This questionnaire is used to determine signs and symptoms, coronary artery disease risk (CAD) factors and information relevant to the subject's safe participation in the research protocol. Refer to ACSM (2014, p. 25) for an example of a health history questionnaire. The health history questionnaire must also include protocol-specific questions to identify additional risks associated with the protocol (e.g., a participant with an implanted electronic device may be at risk in a vibration protocol) or a targeted population (e.g., older adults may be at greater risk for falling in a weight bearing activity).

## <sup>4</sup> Classification of hypertension

Note that either Systolic Blood Pressure (SBP) or Diastolic Blood Pressure (DBP) determines the risk.

	SBP mmHg	DBP mmHg
Normal:	< 120	<80
Prehypertension:	120 to 139	80 to 89
Stage 1 hypertension:	140 to 159	90 to 99
Stage 2 hypertension:	$\geq 160$	>100

*Ref: ACSM (2008); O' Connor et al. (2007)*

## <sup>5</sup> Specific Risks for Resistance Testing or Training

Confirmed or suspected osteoporosis or osteopenia, musculo-skeletal injuries to involved joints, surgery within last year (includes eye surgery), hernia, Marfan syndrome, implanted pacemaker or defibrillator, low functional capacity (<4 METS), uncontrolled hypertension >160/100 mmHg represent a partial list of risks. The researcher must use his or her experience in determining further risk related to a specific protocol. Isometric and dynamic exercise provide a cardiac challenge when sustained. Intensity levels and program design should be modified for those at high risk for CAD. If multiple sets are performed it is recommended to allow >60 seconds between sets for SBP and HR to recover to resting levels in healthy and adults with cardiac disease (Lamotte et al., 2006). *Ref: Pescatello et al. (2004); Williams, 2007*

## <sup>6</sup> Coronary Artery Disease (CAD) Risk

Low, moderate or high CAD risk is determined through knowledge of Major Signs and Symptoms or Known Disease or Condition (see A below); and number of Coronary Artery Disease Risk Factors (see B below).

### **Low CAD Risk**

No major signs or symptoms or known disease and <2 CV risk factors

### **Moderate CAD Risk**

No major signs or symptoms or known disease and  $\geq 2$  CV risk factors

### **High CAD Risk**

$\geq 1$  major sign or symptom or known disease

## **A. Major Signs and Symptoms or Known Disease or Condition**

### 1. Major signs or symptoms suggestive of CV, Pulmonary or Metabolic Disease:

- a. Pain, discomfort in the chest, neck, jaw, arms or other areas that may result from ischemia.
- b. Shortness of breath at rest or with mild exertion.
- c. Dizziness or fainting
- d. Difficulty breathing when lying down or during sleep
- e. Swelling in one or both ankles
- f. Heart rate irregularities
- g. Acute cramp like pain in muscles when exercising that subsides when exercise is stopped
- h. Known heart murmur
- i. Unusual fatigue or shortness of breath with usual activities

### 2. Known Disease or Condition

- a. Cardiovascular: cardiac, peripheral vascular, or cerebrovascular disease
- b. Pulmonary: COPD, asthma, interstitial lung disease, or cystic fibrosis
- c. Metabolic: Diabetes mellitus (Types 1 and 2) or renal disease

*Ref: ACSM (2008, 2010, 2014)*

- d. Thyroid or Liver disease
- e. Other considerations (e.g., pregnancy)

## B. Coronary Artery Disease Risk Factors

Ref: ACSM (2010, 2014)

1. Age: men  $\geq 45$  years, women  $\geq 55$  years.
2. Family History of heart disease: Sudden death, heart attack or coronary revascularization surgery in one or more close relative. Father or brother younger than 55 yr; mother or sister younger than 65 yr.
3. Cigarette Smoking: Current smoker or having quit within the last 6 months, or exposed to environmental tobacco smoke.
4. Sedentary lifestyle: Not participating in at least 30min of moderate intensity physical activity on at least three days of the week for at least three months.
5. Obesity: BMI  $\geq 30$  kg/m<sup>2</sup> or waist girth  $> 102$  cm (40 inches) for men and  $> 88$  cm (35 inches) for women. Allied health professionals ought to use clinical judgment when evaluating this risk factor as thresholds for obesity vary. Individuals with large muscle mass may have a high BMI and waist circumference in the absence of obesity.
6. \*High Blood Pressure: On medication for blood pressure OR blood pressure at or above 140/90 mmHg (either number high) on  $\geq 2$  occasions.
7. \*Blood lipids: On medication for lowering blood lipids OR one of the following: LDL (bad) cholesterol over  $\geq 130$  mg/dl; or HDL (good) cholesterol  $< 40$  mg/dl. If only total cholesterol level available: use  $\geq 200$ mg/dl;
8. \*Prediabetes. Impaired fasting glucose  $\geq 100$  mg/dl but  $< 126$  mg/dl or impaired glucose tolerance test  $\geq 140$  mg/dl but  $< 200$  mg/dl on  $\geq 2$  occasions. Note: glucose  $> 126$  mg/dl represents a *symptom* of metabolic disease, not a risk factor.

### Notes:

- a) \*Blood pressure, blood lipids and glucose should be confirmed on  $\geq 2$  occasions.
- b) If HDL cholesterol  $\geq 60$  mg/dl, subtract one risk factor from total.
- c) If information for a risk factor is not available it should be counted as a risk except for prediabetes. Count missing glucose as a risk factor for men and women  $\geq 45$  years w/ BMI  $\geq 25$  kg/m<sup>2</sup>; and for men and women under 45 who have a BMI  $\geq 25$  kg/m<sup>2</sup> and have one or more additional risk factors for prediabetes (e.g. excess abdominal fat, inactivity, family history of diabetes mellitus).
- d) Missing values are not considered a risk factor if the person has had an assessment of the risk factor (e.g., blood pressure, cholesterol, etc.), does not know his or her numbers, but was told they were acceptable.

CAD risk classification, major signs and symptoms, and CAD risk factors are adapted, with permission, from American College of Sports Medicine. *ACSM's Guidelines for Exercise Testing and Prescription* (8<sup>th</sup> ed.). Philadelphia: Lippincott Williams & Wilkins, 2010, pp. 23, 26-28.

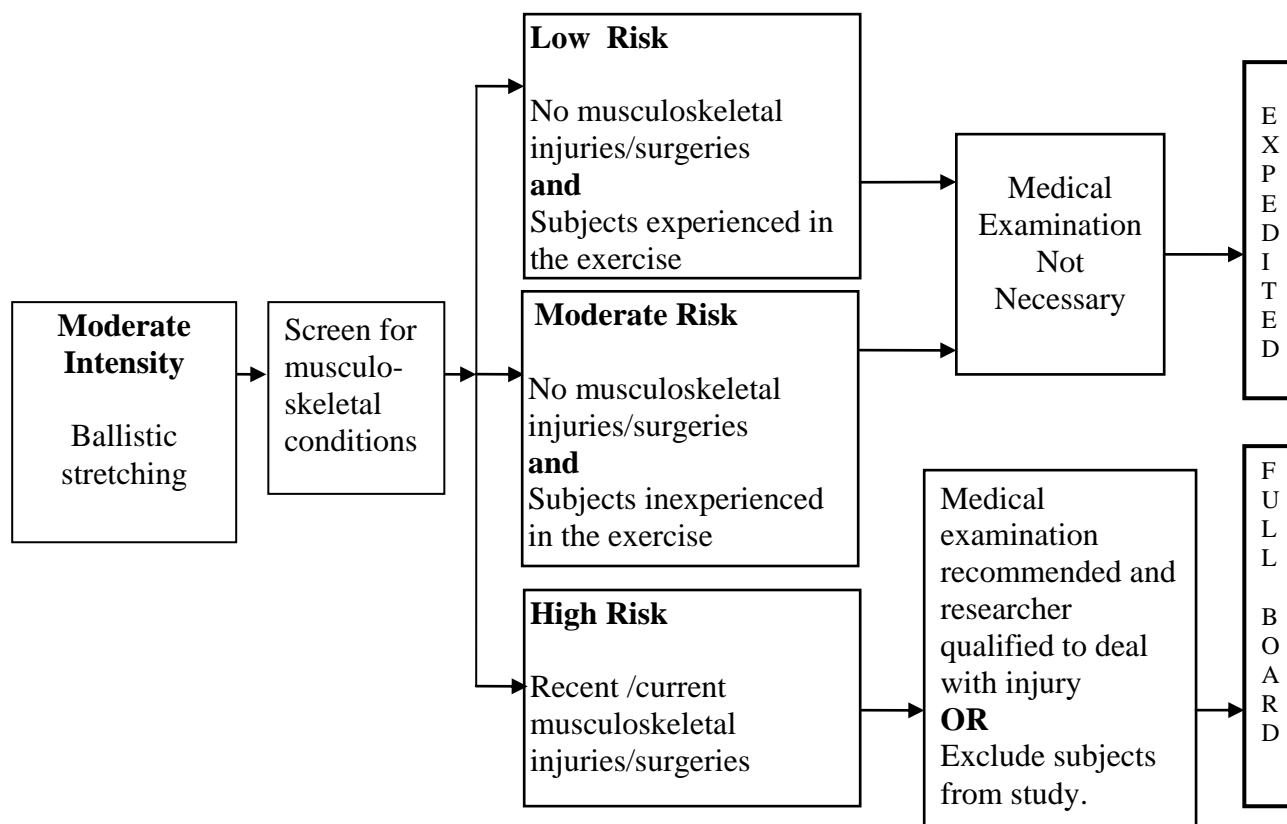
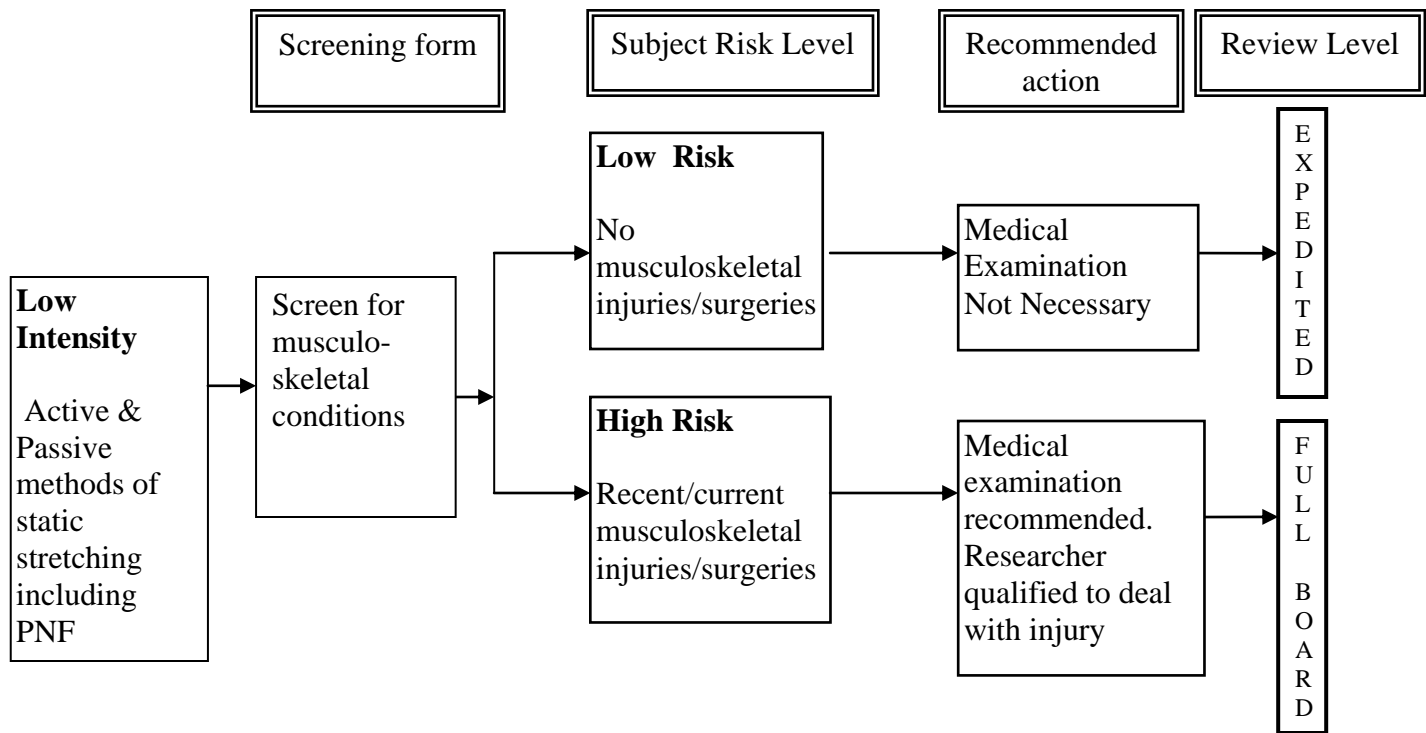
The Exercise Decision Trees serve as guidelines for the Institutional Review Board. If a researcher wishes to deviate from the guidelines s/he must provide justification for any modifications.

Additional screening and monitoring of subjects during and after exercise is required for protocols that include greater stress than is found in traditional resistance strength and testing protocols (e.g., extreme plyometrics, eccentrically induced muscle soreness, programs that could induce exertional rhabdomyolysis etc.).

## REFERENCES FOR IRB STRENGTH/RESISTANCE DECISION TREES

- American College of Sports Medicine. (2014). *ACSM's guidelines for exercise testing and prescription* (9<sup>th</sup> ed.). Philadelphia: Lippincott Williams & Wilkins.
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- Howley, E.T., & Franks, B.D. (2007). *Fitness professional's handbook* (5<sup>th</sup> ed.). Champaign, IL: Human Kinetics.
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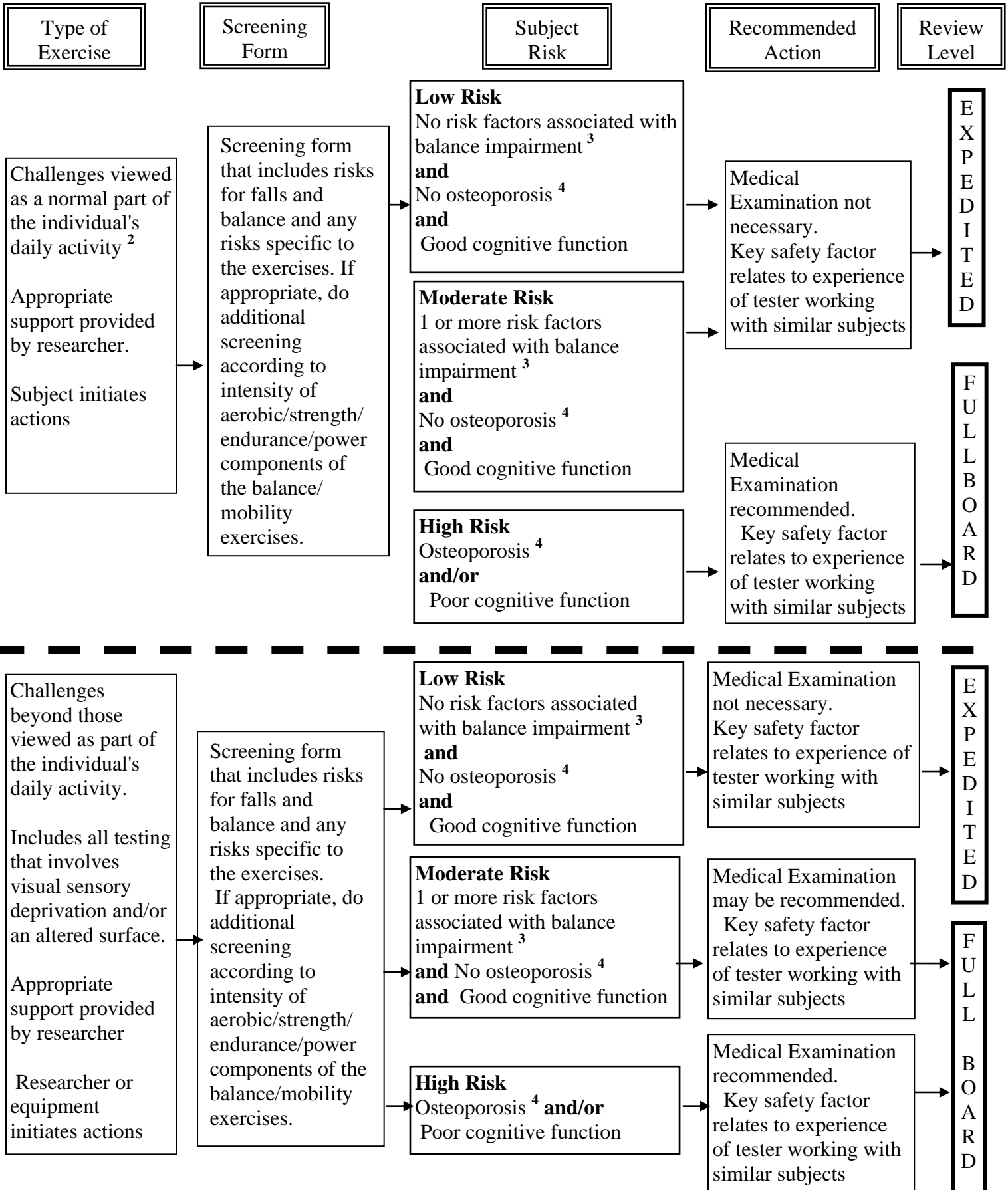
## Flexibility Exercise Decision Tree for Adults (18 years and older)



The Exercise Decision Trees serve as guidelines for the Institutional Review Board. If a researcher wishes to deviate from the guidelines s/he must provide justification for any modifications.



# Balance and Mobility Exercise<sup>1</sup> Decision Tree for Adults (18 years and older)



### <sup>1</sup> Balance and Mobility Exercise.

This includes both static and dynamic exercises that challenge an individual's stability as he or she remains still or moves through the environment. The exercises may include a combination of balance, strength, quickness and ambulatory decision making found in the environment or designed to enhance function.

### <sup>2</sup> Daily Activity.

This includes balance and mobility challenges experienced in the normal environment for the individual. It assumes the subject is at his or her full capacity. Examples: (a) an elderly subject who lives in assisted living walking or standing on a stable surface with eyes open in a lighted room using his or her usual walking aid; (b) a gymnast walking on a beam while looking up; or (c) children playing on an age-appropriate jungle gym.

### <sup>3</sup> Risks for Falls or Balance

The following are some factors that contribute to falls or decrease balance, This is not a comprehensive list that would satisfy all protocols. The number of incidences (e.g., number of recent falls or number of medications) as well as the combination of factors can exponentially increase the risk of falling.

- Vision deficit including cataracts, glaucoma, macular degeneration or other conditions
- Vestibular problems including acute and chronic dizziness or light headedness
- Medications associated with falls including psychotropics, anti- hypertensives and other medications that cause dizziness or have been associated with falls
- Leg weakness due to muscle or nerve loss
- Record of unexplained falls
- Record of falls commonly associated with frailty or low physical function
- Inability to walk and move about safely without a walking aid
- Assistance or nursing care is needed to complete activities of daily living (ADLs)

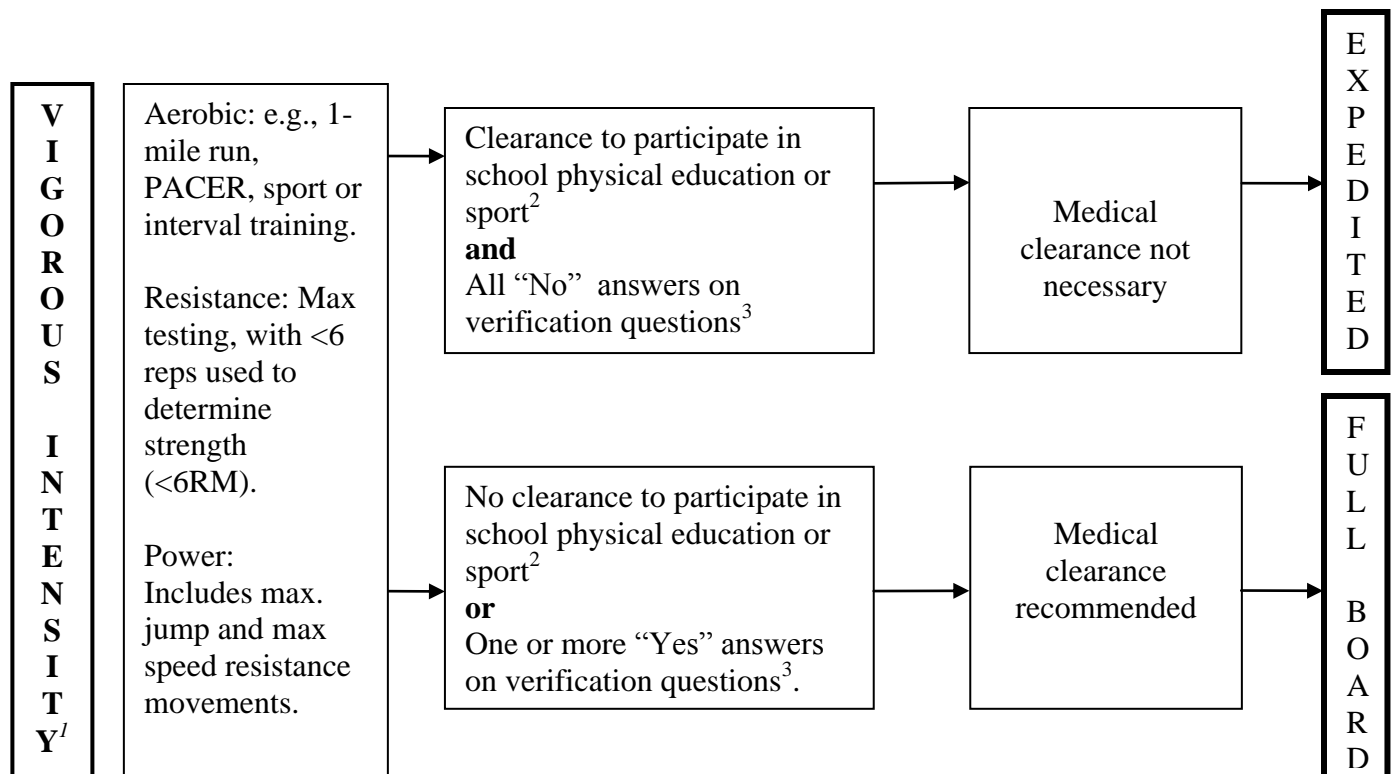
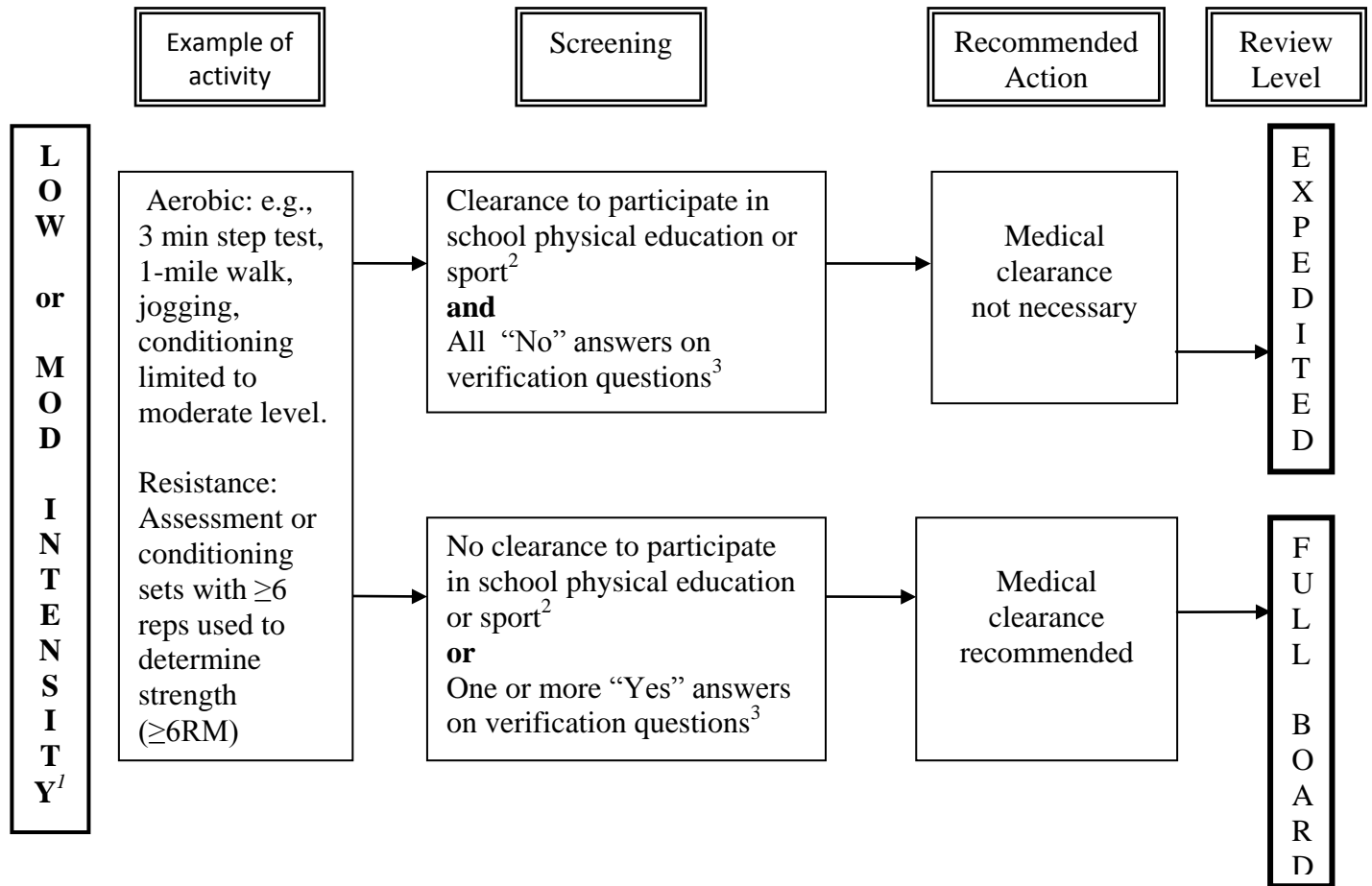
*NOTE:* Osteoporosis and cognitive function are major factors used in determining the subject's risk during an exercise program. Osteoporosis increases the risk of fractures, and limited ability to make good choices during exercise increases chance of injury. Safety precautions must be explicit when including participants with these risks.

### <sup>4</sup> Determination of Osteoporosis or No Osteoporosis.

The researcher will make this determination based on the subject's information on his or her diagnosis of osteoporosis. If a subject has not had a recent bone mineral density assessment and the researcher suspects the subject is at risk for osteoporosis, the researcher is advised to seek more information about this risk.

The Exercise Decision Trees serve as guidelines for the Institutional Review Board. If a researcher wishes to deviate from the guidelines s/he must provide justification for any modifications.

## Exercise Decision Tree for Children and Youth (<18 years old)



## Notes

The guidelines presented relate to school-aged children and youth. For preschool children the following guidelines are suggested:

- a) If the research involves physical activity similar to the child's regular activity levels, no medical clearance is recommended.
- b) If the research involves physical activity of higher intensity than the child's regular activity, medical clearance is recommended.

As part of the parental consent/permission form, the parent needs to confirm that his or her child has medical clearance to participate in physical education or sport without restriction. The parent also needs to answer the verification questions<sup>3</sup>.

Abbreviations			
ACSM	American College of Sports Medicine	HR	Heart rate
BP	Blood Pressure	HRR	Heart rate reserve
CAD	Coronary Artery Disease	RM	Repetition maximum
CV	Cardiovascular	RPE	Rating of perceived exertion
HDL	High density lipoprotein	VO <sub>2</sub> max	Maximal oxygen uptake

### <sup>1</sup> Exercise intensity for Aerobic Exercise.

The following are guidelines. What is light activity for one individual may be vigorous intensity for another (e.g., treading water may be low intensity for a swimmer; however it could be high intensity for a non-swimmer).

*Ref: Modified from Centers for Disease Control and Prevention (2008)*

Test/activity	Light	Moderate	Vigorous
% HR max	35-54	55-69	>70
% HRR or % VO <sub>2</sub> max	20-39	40-59	>60
MET level	<3	3 to <6	≥6
Perception of heart rate and breathing	Minimal increases	Noticeable increases	Substantial increases
Talk test	Could sing	Comfortable conversation	Winded, too out of breath to share a conversation
Borg's 20 point RPE (Borg, 1998)	<12	12-14 "somewhat hard"	15-20 ≥ "heavy (hard)"
Borg's CR-10 Perceived exertion (Borg, 1998)	0-3 "easy"	4-6 "somewhat strong" to "strong (heavy)"	7-10 ≥ "very strong"
Walking	Slow	Brisk	Race walking
Golf	Power cart	Pull cart	Carry clubs
Swimming	Treading water	Recreational swim	Fast lap swim
Gardening	Pruning	Power mower	Hand mower
Housework	Dusting & vacuuming	Scrubbing floors, washing windows	Moving furniture

## <sup>2</sup> Clearance to Participate in School Physical Education or Sport

In order to participate in school physical education, students in Illinois are required to get medical clearance. This is one item on the Illinois Certificate of Child Health Examination form. Parents must submit this form to the school district before students enter pre-kindergarten, kindergarten, 6<sup>th</sup> and 9<sup>th</sup> grades.

An example of the screening form is available at

[http://www.idph.state.il.us/health/vaccine/child\\_hlth\\_forms/Child\\_Hlth\\_Exam\\_Cert.pdf](http://www.idph.state.il.us/health/vaccine/child_hlth_forms/Child_Hlth_Exam_Cert.pdf)

In order to participate in high school sports, athletes in Illinois must receive medical clearance annually. An example of the form used for high school students is available at

[http://www.syc427.org/highschool/departments/Athletic\\_Forms/Pre-participation\\_Examination\\_\(2\).pdf](http://www.syc427.org/highschool/departments/Athletic_Forms/Pre-participation_Examination_(2).pdf)

Both forms require parent or guardian verification.

Children and youth not enrolled in school or students tested in other states should submit a health examination certificate which is comparable to the certificate required in the state of Illinois.

There can be an interval of up to 5 years between physical examinations required for school (and physical education) if a student does not participate in sport. Therefore, a set of verification questions<sup>3</sup> needs to be answered and verified by the parent/guardian in order to determine if the student's health status has changed since the last examination.

### <sup>3</sup>Verification Questions

(Ref: Maron et al., 2007)

1. I am aware of changes to my health since I was cleared to participate in school physical education or in school sports.
2. I experience chest pain or discomfort when I exert myself.
3. I experience excessive or unexplained shortness of breath/fatigue associated with exercise.
4. I experience unexplained fainting or dizziness.
5. I am aware that I have high blood pressure.

Each of these questions must be answered in the negative for the child to participate in the study without medical screening. Note that these questions must be answered by the child with verification by the parent or guardian.

**The Exercise Decision Trees serve as guidelines for the Institutional Review Board. If a researcher wishes to deviate from the guidelines s/he must provide justification for any modifications.**

## **Things to Consider When Undertaking Research with Children And Youth**

Most children are healthy and can safely participate in exercise; however, they must not be treated as small adults (ACSM, 2014). Prior to testing and/or training children it is recommended that researchers who are unaccustomed to working with children in physical activity settings read (a) “Differences between Children and Adults for Exercise Testing and Prescription” by H. Hebestreit and O.Bar-Or; and (b) “Children aren’t miniatures adults: Similarities and differences in physiological responses to exercise (Parts I and 2)” by S. Plowman.

### **Ability to Be Discerning**

Information must be conveyed to children at a level they can understand if they are to assent to participate. Consider using images, video, or taking extra time describing the procedures to assist the child in his or her understanding of the research expectations.

The value of rewards and inter-subject competitiveness differs between children and adults.

Children may be intimidated by adults so they may not feel able to withdraw or stop participation when appropriate. Consider the courage it might take for a young child to stop participation while hooked up to the metabolic cart with white-coated, adult strangers verbally encouraging him/her to work harder.

### **Do No Harm**

This includes doing no emotional harm. Guard against embarrassing children (e.g., selecting or excluding the children with some known condition or disability), or decreasing their enjoyment of activity by testing or training with methods that make them feel uncomfortable or unsuccessful.

### **Environment**

A child may respond differently in a new environment which might include (a) the physical space (classroom, playground, sports field, lab); (b) social structure (with peers, alone, or in a competitive environment); and (c) authority figure (teacher, parent, researcher).

### **Intensity**

Consider whether the intensity is initiated by the child (free running or cycling) or externally (on a treadmill). Also consider the duration. Children 6 to 17 years old should not be asked to perform sustained vigorous intensity exercise (ACSM, 2014). It is acceptable for healthy children to perform health/fitness testing, such as the FITNESSGRAM outside of a clinical setting (ACSM, 2014). This test battery does include some test items where children perform to volitional fatigue. Healthy children can perform 1- repetition maximum strength tests if they are properly trained and monitored (Faigenbaum, Milliken, & Westcott, 2003).

### **RPE**

With adequate practice RPE may be used in children to prescribe exercise intensity. The Omni scales (Robertson et. al., 2000) may be better to use with children, especially youngsters less than 9 years old. Children may respond to images better than to a verbal scale.

### **Thermoregulation**

Children are less efficient at dissipating heat than adults so exercising in hot humid conditions should be avoided (ACSM, 2014). Hypo-hydrated children are at risk for heatstroke and other heat related illnesses. Suggest fluid replacement be observed every 15 to 20 minutes during prolonged bouts of exercise. Using a flavored drink enhances fluid intake in children. Children who are obese, hypo-hydrated, wear protective clothing, are malnourished, anorexic, and/or have cystic fibrosis, type I diabetes, a fever, gastroenteritis, or mental retardation are all at additional risk for heat- related illness.

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## SAMPLE LANGUAGE FOR CONSENT FORMS

The following are some suggested considerations the subject needs to know about the research. Topics and details are for researcher consideration and may or may not be pertinent to any specific protocol. If the information below relates to the risk and/or benefit of the subject's participation, it **MUST** be included in the IRB application.

### ***Training and Experience of Researchers***

The researchers have the training and experience to direct the study's procedures. Specifically ... (*give training, certifications, and/or experience of the person who will be performing the testing or training particularly if the subject will be at risk during the activity.*)

### ***Termination Language***

I understand how the researcher will encourage me to perform my best. I understand that I can withdraw from the study at any time without penalty and also that the researcher has the right to terminate or restrict my participation at any time. I may request at the time of withdrawal that all my data be excluded from the research.

### ***Responsibility of Subject***

It is my responsibility to notify the researcher if I experience dizziness, nausea, lightheadedness, unusual pain, or any response that I find unusual or unexpected during or after exercise. I will do what I think is safe for me and will not push myself too far.

### ***Pretesting preparation.***

I will follow (or will have followed) the guidelines given me for pretesting preparation. This includes (eating, drinking, exercise, etc).

### ***Sub-maximal or Maximal Aerobic Exercise or Testing***

With any exercise, there is the possibility that abnormal responses could occur. These include unexpected changes in blood pressure, irregular heart rate, fainting, shortness of breath, fatigue, muscle cramps, muscle soreness or joint injury, and in rare cases, a cardiac event. Risks will be minimized by researchers evaluating a pre-exercise health screening, implementing a standardized exercise protocol (warm-up and cool down), and having an emergency plan in place to follow if needed.

### ***Muscular Strength / Endurance / Power***

With any exercise, there is the possibility for abnormal responses to occur. These include unexpected changes in blood pressure, irregular heart rate, fainting, shortness of breath, muscle cramps, muscle soreness, muscular strain or joint injury, and in rare cases, a cardiac event. Risks will be minimized by researchers evaluating a pre-exercise health screening, and implementing a standardized exercise protocol (warm-up and cool down). An emergency plan is in place and will be followed if needed.



### **Body Composition**

Underwater Weighing: There is a possibility of falling while entering or leaving the underwater weighing tank, and a possibility of becoming anxious when exhaling with my head under water.

Bioelectrical Impedance: There is a possibility of irregular heart rate or that an implanted electronic device may malfunction when a low voltage electrical current is passed through the body. I will not participate if I have an implanted electronic device (e.g., pacemaker, cochlear implant) or if I am pregnant.

Skinfolds: There may be slight discomfort as the calipers pinch the skin. This could result in redness and bruising of the skin at the skinfold site. There may also be some mild social discomfort as the researcher pinches skin at (name sites). This risk will be minimized by testing in a private area.

Bod Pod: There is a possibility some mild anxiety might develop while sitting in a small enclosed capsule.

### **Range of Motion (Flexibility)**

With any exercise, there is the possibility for abnormal responses to occur. These include muscle soreness, and muscular strain or joint injury. Risks will be minimized by researchers evaluating a pre-exercise health screening. An emergency plan is in place and will be followed if needed.

### **Balance**

There is a possibility of falling which could result in injury. The risk will be minimized by researchers evaluating results from a pre-exercise health screening and providing appropriate support to subjects during the balance challenge. Support will include (e.g., *stable rails, a trained assistant in close proximity, physical support, and/or a belt or harness*). An emergency plan is in place and will be followed if needed.

### **Exercise in Heat**

With any exercise, there is the possibility for abnormal responses to occur. These include unexpected changes in blood pressure, irregular heart rate, fainting, shortness of breath, fatigue, muscle cramps, muscle soreness, muscular strain or joint injury, and in rare cases, a cardiac event. There could be some discomfort or reaction associated with a temperature probe or pill. Risks will be minimized by researchers evaluating a pre-exercise health screening, and having an emergency plan in place to follow if needed. The activity will be terminated if my core temperature exceeds ...(*insert temperature and reference or use 103 degrees Fahrenheit.*)

### **EMG**

In order for surface electrodes to have good contact with the skin, the skin will be cleaned and shaved, if necessary, prior to electrode placement which may result in a slight abrasion and soreness. There is a small chance for infection, but this risk will be minimized by following standard hygiene practices.

### ***Sample order of consent form information***

- 1. Provide short description of the research (one paragraph)*
- 2. Explain why the research is important*
- 3. List the benefits the individual subjects might expect*
- 4. Describe what they will be expected to do*
- 5. Describe how the data will be shared and protected*
- 6. Describe all risks to subjects*
- 7. Describe emergency procedures*
- 8. State the subjects can withdraw at any time and researcher can terminate participation*
- 9. Invite questions at any time*
- 10. Include contact information for more information (researcher and NIU IRB)*
- 11. Include signature line*
- 12. Include Video/ audio-recording signature line if appropriate*
- 13. Include Use of images for presentation, teaching etc. signature line if appropriate*

**For more consent form and special consideration examples, look at other universities' IRB websites.**

*Last modified January 4, 2010*

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FORM LANGUAGE

Last Modified July 17, 2013

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