Standard Operating Procedures For Assuring Subject Safety During Research Involving Exercise Testing in the Exercise Physiology Laboratories

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Subject and Exercise Test Risk Stratification

This item needs to be defined and clarified first, as we propose personnel and equipment needs for exercise tests to maximal exertion based on the type of subject we test, and the level of exertion required during the test.

a) Exercise Tests

The potential cardiovascular and muscular-skeletal risks associated with exercise testing increase with increases in exercise intensity. Exercise testing can be submaximal, where the test ends at a pre-determined level of exertion (based on oxygen consumption, rating of perceived exertion, or heart rate), thereby preventing maximal exertion. Conversely, exercise tests can be maximal, where the subject reaches a level of exertion that can no longer be sustained. In addition, exercise tests are not all based on endurance-related exercise (low intensity or incremental walking, cycling, running). We also conduct tests of muscular strength and power involving short bouts of intense exercise (resistance exercise using free weights, weight machines, and isokinetic muscle function), or use short (0.5 to 3 min) of intense running or cycling to quantify a subject's anaerobic energy capacity.

The risks to subject health when completing exercise tests, of all possible types in the EPL, are summarized in Table 1.

Table 1. Risk stratification of all possible exercise tests conducted in the EPL.

Exercise Test	Risk Stratification^		
	Minimal	***Incremental***	***Significant***
Flexibility	✓		
Submaximal exercise	✓		
VO_2max	✓		
Anaerobic capacity	✓		
Muscular strength or power	✓		

^not including added risk due to subject characteristics
Submaximal exercise tests are used to measure steady state metabolism, or predict VO_2max, etc.
VO_2max=maximal rate of oxygen consumption, and is measured at the end of an exercise test, typically between 8-20 min in duration, ending in volitional fatigue
Anaerobic capacity=capacity of energy production from skeletal muscle glycolysis and phosphagen systems. Can be indirectly assessed through intense exercise for 30 s (eg. Wingate test), or 2-3 min of intense exercise (Accumulated O_2 deficit, AOD)

As risk stratification also involves the type of subject being tested, details of pre-screening of subjects will be provided next, followed by a summary of proposed subject-test requirements.

b) Subjects

Based on data available from research and the ACSM guidelines, detailed pre-screening of subjects for potential health-related risks to exercise testing is essential to reduce potential risk to subjects. The following procedures are proposed for specific subject populations;

Completion of the revised EPL health-history questionnaire.

For males <40 years and females <50 years, no additional pre-screening is required.

For males ≥40 years and females ≥50 years, results (within the last 12 months) of fasting (12 hr) blood lipid and glucose profiles are required, and blood pressures (both arms) are to be performed in the EPL.

Weekly physical activity/exercise hours from the health-history questionnaire. Based on this data, subjects will be assigned to one of 5 groups;

Sedentary: less than the minimal recommendations for daily physical activity (≤30 min/day, 5 days/week = ≤2.5 hrs/week)

Low: >2.5 and ≤5.0 hrs/week, with no moderate to intense exercise

Moderate: >2.5 and ≤5.0 hrs/week, including 0.5-1.5 hr/week moderate to intense exercise

High: >5.0 hrs/week, including >1.5 hrs/week moderate to intense exercise

Trained: organized endurance and or strength training (>30 min) performed >5 times/week, including at least 3 sessions (>30 min/each) of intense exercise (>85% VO_2max; cannot be sustained indefinitely).

The stratification of risk based on physical activity/exercise is presented in Table 3.

Table 3. Proposed risk stratification for physical activity/exercise, consistent with terminology of the CDC and ACSM, of subjects to be used for all research-based exercise testing in the EPL.

Activity/Exercise Status	**Risk Stratification^**		
	Minimal	***Incremental***	***Significant***
Sedentary=<2.5 hrs/week		✓	
Low Activity=2.5-5 hrs/week		✓	
Moderate Activity=2.5-5 hrs/week	✓		
High Activity=>5 hrs/week	✓		
Trained	✓		

Based on this screening, the following risk stratification (Table 4) is proposed.

Table 4. Proposed risk stratification, consistent with Federal Guidelines for human subjects research, of subjects to be used for all research-based maximal/intense exercise testing* in the EPL.

Subjects	Risk Stratification		
	Minimal	***Incremental***	***Significant***
Physician Required	NO	NO	YES
12 Lead ECG Required	NO	YES	YES
3 Lead ECG Required	YES		
AED Required	NO	YES	YES
1. Males <40, Females <50			
No CV risk factors			
Sedentary		✓	
Low Activity		✓	
Moderate Activity	✓		
High Activity	✓		
Trained	✓		
1 risk factor			
Sedentary		✓	
Low Activity		✓	
Moderate Activity		✓	
High Activity	✓		
Trained	✓		
2 or more risk factors			
Sedentary			✓
Low Activity			✓
Moderate Activity			✓
High Activity			✓
Trained			✓
2. Males ≥40, Females ≥50			
Regardless of risk factors			✓

*pertains to VO_2max, Wingate and Anaerobic capacity tests, and muscular strength

Equipment Needs

The EPL is already very well equipped. We have 12-lead ECG capabilities to support two exercise-testing locations, and numerous treadmills, ergometers and expired gas analysis systems. However, we have one AED device for the entire lab. We are currently arranging for funds (~$3,000) to purchase a second AED device so that we have one assigned to each of our two ECG-based testing locations within the lab, and the option of taking one to the altitude chamber facility.

Personnel Qualifications

At least one person involved in exercise testing is required to have each of the following;

Successful completion of a degree in exercise science/physiology.

External certification by either the American College of Sports Medicine, or the American Society of Exercise Physiologists.

Red Cross First Aid and Automated Electrical Defibrillator (AED) certification.

Successful completion of the Exercise Science course in electrocardiography (PEP475).

Successful completion of the in-service sessions on AED and ECG offered during the week prior to each semester.

Participation in EPL emergency procedure drills held each semester.

The personnel who do not meet all of items 1-5 above should be qualified such that items 3, 4 and 5 are met in case of a cardiovascular emergency. For example, a testing technician other than the complete qualified person needs to have either first aid and AED certification, or competence in ECG, and participate in the in-service sessions for either component. The number of personnel required for a maximal exercise test, based on the risk stratifications of Table 4 are detailed in Table 5.

Table 5. Number of personnel required for all exercise testing in the EPL. Not including a physician, when required based on risk stratification.

Exercise Test/Risk Stratification	Exercise Test and Personnel Numbers			
	Flexibility	***CE****	***TR***	***Resistance***
Submaximal				
Minimal	1	1	1	1
Incremental	1	1	1	1
Significant	1	2	2	2
VO_2max				
Minimal		1	2	
Incremental		2	2	
Significant		2	3	
Anaerobic Capacity[#]				
Minimal		1	2	
Incremental		2	2	
Significant		2	3	
Muscular Strength and Power				
Minimal				1
Incremental				1
Significant				2

*assumes automated gas analysis and ergometer. If not, for all tests other than sub-maximal add 1 person

[#]for the Wingate test and the 2-3 min intense bout of the AOD test

Rationale

The proposed risk stratification criteria of table 4 reveal a heightened protection to subjects by;

1. reducing the cut-off ages for requiring the presence of a physician by 5 years for each of males (45 to 40 years) and females (55 to 50 years).
2. requiring 12-lead ECG assessment during exercise tests/subjects providing incremental and significant risk.
3. requiring 3-lead ECG assessment during exercise tests/subjects providing minimal risk.

4. requiring the presence of an AED for tests/subjects providing incremental and significant risk.
5. using an objective assessment of physical activity/exercise to include in the classification of subject risk during exercise testing.
6. application of the criteria to all testing requiring intense exercise; tests to VO_2max, tests of muscle power and strength, and tests of anaerobic capacity.
7. the requirement of actual tests results for blood lipids and glucose (within 12 months), and blood pressures for all subjects above the age cut-off criteria.
8. the purchase of an additional AED device for the EPL. This unit will also be used in the altitude research facility when testing pertinent subjects, allowing for one unit to always remain in the EPL.
9. establishing personnel qualifications and numbers of personnel required for specific exercise tests, and specific risk categories.
10. developing and implementing AED and ECG in-service sessions each semester.
11. extending current emergency procedure drills to all students and faculty involved in research-based exercise testing.

References

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