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\textsubscript{2} 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\textsubscript{2} 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**


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