

UWO – HSREB	GUIDELINE	2-G-011	Page 1 of 2
Effective date: 03-02-01	Research Exercise Protocols that result in a measurable change in a research participant's cardiovascular and/or respiratory dynamics.		

Researchers with questions as to whether or not their research would fall under these guidelines should contact the Director of the UWO Office of Research Ethics for a ruling. Please provide a brief written description of the exercise activity, the research participants and anticipated physiological response(s).

All research exercise protocols resulting in a measurable change in the subject's cardiovascular and/or respiratory dynamics must :

1. adhere to established and generally accepted standards. (e.g. The American College of Sport Medicine's Guidelines for Exercise Testing and Prescription; the American Heart Association's Scientific Statement on 'Exercise Standards for Testing and Training', 2001 etc).
2. document in the ethics protocol submission what standard the protocol adheres to and if it is not fully compliant with that standard, why not.
3. have at least one person who is trained in, and familiar with normal and abnormal responses during exercise, and possess a current CPR certificate, present in the general exercise area and aware that a participant is engaged in the exercise intervention.
4. have a clear plan that is to be followed by the investigators in the event of a medical emergency. All research personnel must be made aware of this plan and it should be posted in a readily accessible area. Researchers should address this plan in the ethics protocol submission section dealing with Protection of Health and Safety of Participants.
5. identify what procedures, equipment and staff are in place to deal with medical emergencies if the exercise testing is being conducted at a site that is not within or adjacent to a medical facility (i.e. a hospital). (i.e. it is not acceptable to say in the ethics protocol submission that a crash-cart or resuscitation equipment are available, if there is no one trained in their use available at testing times.) Researchers should address these issues in the ethics protocol submission section dealing with Protection of Health and Safety of Participants.

All exercise protocols involving subjects at increased medical risk must also adhere to Points 7 through 10 of this guideline.

Even though pregnancy does not automatically constitute an increased medical risk. All pregnant women:

6. should be under the prenatal supervision of a licensed physician or midwife during the period of the study. This clinical supervisor should be aware of the request for the subject's participation in the study and be provided sufficient detail of the exercise intervention to permit appropriate assessment of its impact on the subject's health. Approval of the supervising clinician should be provided in writing prior to commencement of the study.

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Those considered to be at increased medical risk include persons that meet one or more of the following criteria:

- A. Are 50 years of age or older;
- B. Have a medical history involving diseases of, or significant symptoms suggesting possible diseases associated with, the cardiovascular or respiratory system;
- C. Have any health circumstance (e.g. significant obesity, smoking etc.) that might compromise an individual's normal healthy adaptation to exercise;
- D. Are not regularly exercising to the intensity described in the intervention of the protocol.

All exercise protocols resulting in a measurable change in a person's cardiovascular and/or respiratory dynamics and involving subjects at increased medical risk must :

7. include the requirement that a general medical assessment be conducted by a licensed physician familiar with the proposed research procedures. This assessment should include particular emphasis on, and appropriate diagnostic tests related to, the cardiovascular and respiratory systems and provide medical clearance for the subject to participate in the proposed research if appropriate.
8. have the assessment completed before the study commences, documented in writing and signed and dated by the assessing physician. A copy should be retained with the subject's research study records.
9. have a licensed physician present in the general exercise area when an 'at increased medical risk' participant is engaged in the exercise intervention and ensure this physician is made aware that an 'at increased medical risk' participant is engaged in the exercise intervention.
10. name a licensed physician as a co-investigator or collaborator on the ethics protocol submission.

Ongoing protocols that received HSREB approval prior to February 1, 2003:

It is strongly recommended that any participants recruited after February 1, 2003 to an ongoing exercise protocol relevant to the intervention conditions of the guidelines, be assessed under these guidelines. If the investigator is not able to comply with this recommendation s/he must write to the REB to request an exception.