

Research Guidance Document

EXERCISE TESTING IN RESEARCH

Description

When exercise testing is used as part of a research study, investigators must provide the IRB with information regarding the safety plan.

Investigators should describe the process and mechanisms in place for assuring the safety of research participants during exercise testing. Investigators should consider whether exercise testing may expose the participants to greater risk based on their physical fitness level and general health. When preparing a safety plan, investigators may consider participants':

- Physical condition, age and level of training (e.g. a competitive runner versus a non-runner)
- The presence or absence of any known cardiovascular, pulmonary or metabolic disease.
- The presence or absence of any signs or symptoms suggestive of cardiovascular, pulmonary or metabolic disease.
- The presence or absence of cardiovascular disease risk factors.

Based upon the risk factors of the participants and the intensity of the exercise, the safety plan may require (1) a physical examination by M.D. or N.P. prior to exercise testing and (2) physician supervision of exercise testing. Investigators may consider referring to the current ACSM's Guidelines for Exercise Testing and Prescription.

Points to Address

Application:	 Study Information Page (Procedures): If participants will be required to undergo exercise testing, describe when testing will take place, and what procedures the testing will entail. Please note that a distinction should be made between the procedures for treatment evaluation verses procedures for safety evaluation. Study Information Page (Procedures): Describe the process and mechanisms in place for assuring the safety of research participants during exercise testing. Please note that you may be required to provide a safety monitoring plan.
Consent Document:	 Procedures: If participants will be required to undergo exercise testing, describe when testing will take place, what procedures the testing will entail, and how long testing will take to complete. Procedures: Please state whether or not participants will receive the results of their exercise test(s).

References & Links

American College of Sports Medicine

http://www.acsm.org