EXERCISE TESTING IN RESEARCH

Description

When exercise testing is used as part of a research study, the IRB requires a safety plan which may include: a physical examination by M.D. or N.P. prior to exercise testing and/or physician supervision of exercise testing. 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 planning to conduct exercise testing as part of a research project 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, and the presence or absence of cardiovascular disease risk factors.

The ACSM provides a comprehensive method to evaluate the risk level of an individual and the level of exercise. In summary, participants fall into one of three risk categories: low, moderate, or high risk. The risk category is based upon:

- 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.

Once the determination is made for the risk category of the participants, the intensity of the exercise is factored into the risk stratification to determine whether a physical examination by M.D. or N.P. prior to exercise testing and/or physician supervision of exercise testing is required. Based upon the risk factors of the participants and the intensity of the exercise, the safety plan may require a physical examination by M.D. or N.P. prior to exercise testing and/or physician supervision of exercise testing.

Points to Address

Application:

1. 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 versus procedures for safety evaluation.

Consent Document:

1. 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.

2. 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

Please contact the IRB office at 801-581-3655 or irb@hsc.utah.edu for additional guidance.
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IGS: Exercise Testing in Research
Version 2016
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