



Guidance: Exercise testing in human subject research

Overview

When exercise testing is used as part of a human subject research study, investigators should consider whether procedures may expose the participants to greater risk based on their physical fitness level and general health. In some circumstances, a safety plan should also be developed in the event of injury.

Protocol

If participants will be required to undergo exercise testing, include a description of when testing will take place and what procedures the testing will entail. 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. The protocol should also detail how risks will be mitigated and the plan, including notifying the IRB, should an unforeseen or adverse event occur.

Normal training vs. research

If procedures and data collection coincide with a participant's or team's training, clearly identify which procedures or exercises are part of the participants' "normal" or "required" training and which procedures have been added exclusively for research purposes.

Safety plan

The safety plan should describe the process and mechanisms in place for assuring the safety of research participants during exercise testing. The following should be considered when developing a safety plan:

- Physical condition, age and level of training (e.g., a competitive runner versus a non-runner)
- The presence or absence of cardiovascular disease risk factors.
- 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.
- 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.*

The research team must promptly report to the IRB should any injury occur during any research involving exercise or training.

Consent form: Procedures section

- Where the activities are performed and how frequently they are performed.
- The expected amount of time each activity and/or visit will last.
- Specify which activities are normal and required training and which ones are solely research activities.
- Provide information on training, certifications, and/or experience of the person who will be performing the testing or training, including CPR/First Aid.
- State whether participants will receive the results of their exercise test(s).



Consent form: Sample text for Risks section

Sub-maximal or Maximal Aerobic Testing & Muscular Strength/Endurance/Power

“With any exercise, there is the possibility that abnormal responses could occur. These include unexpected changes in blood pressure, irregular heart rate, fainting, shortness of breath, fatigue, muscle cramps, muscle soreness or joint injury, and in rare cases, a cardiac event. Risks will be minimized by researchers evaluating and implementing a standardized exercise protocol (warm-up and cool down) and having an emergency plan in place to follow if needed.”

Body Composition

Skinfolds: “There may be slight discomfort as the calipers pinch the skin. This could result in redness and bruising of the skin at the skinfold site. There may also be some mild social discomfort as the researcher pinches skin at (name sites). This risk will be minimized by testing in a private area.”

Bod Pod: “There is a possibility some mild anxiety might develop while sitting in a small, enclosed capsule.”

Range of Motion (Flexibility)

“With any exercise, there is the possibility for abnormal responses to occur. These include muscle soreness, and muscular strain or joint injury. An emergency plan is in place and will be followed if needed.”

Balance

“There is a possibility of falling which could result in injury. The risk will be minimized by researchers providing appropriate support to subjects during the balance challenge. Support will include (e.g., stable rails, a trained assistant in close proximity, physical support, and/or a belt or harness). An emergency plan is in place and will be followed if needed.”

References & Resources

Resources & References

[American College of Sports Medicine](#)

[ACSM’s Guidelines for Exercise Testing and Prescription](#)