SAMPLE LANGUAGE FOR CONSENT FORMS

The following are some suggested considerations the subject needs to know about the research. Topics and details are for researcher consideration and may or may not be pertinent to any specific protocol. If the information below relates to the risk and/or benefit of the subject’s participation, it MUST be included in the IRB application.

Training and Experience of Researchers
The researchers have the training and experience to direct the study’s procedures. Specifically … (give training, certifications, and/or experience of the person who will be performing the testing or training particularly if the subject will be at risk during the activity.)

Termination Language
I understand how the researcher will encourage me to perform my best. I understand that I can withdraw from the study at any time without penalty and also that the researcher has the right to terminate or restrict my participation at any time. I may request at the time of withdrawal that all my data be excluded from the research.

Responsibility of Subject
It is my responsibility to notify the researcher if I experience dizziness, nausea, lightheadedness, unusual pain, or any response that I find unusual or unexpected during or after exercise. I will do what I think is safe for me and will not push myself too far.

Pretesting preparation.
I will follow (or will have followed) the guidelines given me for pretesting preparation. This includes (eating, drinking, exercise, etc).

Sub-maximal or Maximal Aerobic Exercise or Testing
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 a pre-exercise health screening, implementing a standardized exercise protocol (warm-up and cool down), and having an emergency plan in place to follow if needed.

Muscular Strength / Endurance / Power
With any exercise, there is the possibility for abnormal responses to occur. These include unexpected changes in blood pressure, irregular heart rate, fainting, shortness of breath, muscle cramps, muscle soreness, muscular strain or joint injury, and in rare cases, a cardiac event. Risks will be minimized by researchers evaluating a pre-exercise health screening, and implementing a standardized exercise protocol (warm-up and cool down). An emergency plan is in place and will be followed if needed.
**Body Composition**

**Underwater Weighing:** There is a possibility of falling while entering or leaving the underwater weighing tank, and a possibility of becoming anxious when exhaling with my head under water.

**Bioelectrical Impedance:** There is a possibility of irregular heart rate or that an implanted electronic device may malfunction when a low voltage electrical current is passed through the body. I will not participate if I have an implanted electronic device (e.g., pacemaker, cochlear implant) or if I am pregnant.

**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. Risks will be minimized by researchers evaluating a pre-exercise health screening. 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 evaluating results from a pre-exercise health screening and 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.

**Exercise in Heat**
With any exercise, there is the possibility for abnormal responses to occur. These include unexpected changes in blood pressure, irregular heart rate, fainting, shortness of breath, fatigue, muscle cramps, muscle soreness, muscular strain or joint injury, and in rare cases, a cardiac event. There could be some discomfort or reaction associated with a temperature probe or pill. Risks will be minimized by researchers evaluating a pre-exercise health screening, and having an emergency plan in place to follow if needed. The activity will be terminated if my core temperature exceeds ... (insert temperature and reference or use 103 degrees Fahrenheit.)

**EMG**
In order for surface electrodes to have good contact with the skin, the skin will be cleaned and shaved, if necessary, prior to electrode placement which may result in a slight abrasion and soreness. There is a small chance for infection, but this risk will be minimized by following standard hygiene practices.
Sample order of consent form information

1. Provide short description of the research (one paragraph)
2. Explain why the research is important
3. List the benefits the individual subjects might expect
4. Describe what they will be expected to do
5. Describe how the data will be shared and protected
6. Describe all risks to subjects
7. Describe emergency procedures
8. State the subjects can withdraw at any time and researcher can terminate participation
9. Invite questions at any time
10. Include contact information for more information (researcher and NIU IRB)
11. Include signature line
12. Include Video/ audio-recording signature line if appropriate
13. Include Use of images for presentation, teaching etc. signature line if appropriate

For more consent form and special consideration examples, look at other universities’ IRB websites.

Last modified January 4, 2010