Application Number: 2009F4082  
  
02/13/10 13:29:39   
I made an error with my original evaluation, confusing the documents from this application with another, similar application.  My comments for this application are below:  
  
Although some aspects of the form have been revised, the form still includes many terms that might be difficult.  For example:  
  
1.      Pre-participation information: Subjects will complete a pre-participation questionnaire with 20 questions as well as a brief orthopedic assessment to get general joint range of motion by a certified athletic trainer.   
  
Many people may not understand the terms \"pre-participation\" and \"orthopedic.\"  Please rephrase them for participants.

Revision:

**Pre-participation information**: Before participation in the study, each subject will complete a questionnaire with 20 questions about the subject’s general health and history of injuries. A certified athletic trainer will also determine if the subject has the physical capability to complete the study by measuring general joint motion and checking the alignment of the spine, arms, and legs.

3.      NeuroCom:  The subjects will be fitted for a safety harness and will step onto the NeuroCom force plate in order to complete a baseline balance measurement.   
  
Please describe this process in laymen\'s terms for people who do not know what a NeuroCom force plate and saftey harness are.

Revision:

**NeuroCom**: The subjects will be fitted for a safety harness which is a vest with straps that attach to the top of the NeuroCom machine and will prevent the subject from falling. The NeuroCom is a machine used to measure balance. It has a balance plate approximately the size of a bathroom scale that the subject will stand on.

4.      Biodex set up: The subjects will then sit in the Biodex chair to allow the principle investigator to set up the lever arms at the appropriate area to allow the patient to plantar flex and dorsiflex their foot.   
  
Please explain, in laymen\'s terms, what the Biodex chair is, and what plantar flex and dorsiplex of the foot are.

Revision:

**Biodex set up**: The Biodex is an exercise machine used to measure the power of the subject’s leg. The subjects will sit in the Biodex chair while the principal investigator to set up the lever arms at the appropriate area to allow the patient to point toes down as far as possible and then bring toes as far up to shin as possible.

5.  Principal investigator is \"principal\", not \"principle.\"

Revision:

~~Principle~~ Principal

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Please see the comments below and submit revisions, along with a document that details how you addressed the concerns, item by item.  
  
02/09/10 15:49:42  
A few minor revisions are needed.  
  
1.  Please include faculty supervisor name, position, and contact information in the consent form.  
Revision added to consent form:  
Faculty Supervisor: Jack Ransone, PhD, Professor of Athletic Training. Dr. Ransone may be contacted by email: ransone@txstate.edu, or phone: 512-245-8176.  
  
2.  Note that participants may stop participation at any time, and that they may ask for their data to be removed from the study (in the consent form).  
Revision added to consent form:  
You may choose to stop the procedures at any time for any reason.  
  
3.  Note how long data will be kept in the investigator\'s office (and what steps will be taken to avoid a loss of confidentiality--e.g., locked file, etc.).  
Revision added to consent form:  
All data from the research will be kept in the supervisor’s office in a locked file cabinet to avoid loss of confidentiality.  In order to maintain confidentiality, the recorded data will be kept for up to 5 years total.  After this 5 year period, all information and data will be destroyed.  
  
01/06/10 18:05:26  
This is a well-written application. The application could be improved by addressing the following points:  
  
1. Specify who is responsible for covering medical expenses incurred in the event that the participant requires medical attention.  
Revision added to consent form:  
If an emergency occurs during testing, the subjects will be instructed to exit the building immediately.  If it is a medical emergency, then emergency services will be contacted.  The primary investigator is Professional Rescuer Certified and will assist with all emergency situations until EMS arrives on the scene.  In the event that the participant will require medical attention, the participant will be responsible for covering all medical expenses.  
  
2. Add in a statement that participants may choose to stop the procedures for any reason.  
Revision added to consent form:  
Your participation is strictly voluntary and you may choose to stop any of the procedures at any time for any reason.  
  
3. The location and length of time the survey data, videotapes, audio recordings etc. will be kept must be explicitly stated.  
Revision added to consent form:  
All data from this project will be kept in the supervisor’s office in a locked file cabinet to avoid loss of confidentiality.  In order to maintain confidentiality, the recorded data will be kept for up to 5 years total.  After this 5 year period, all information and data will be destroyed.  
Please let me know if I can make any more revisions to better my consent form.