**Informed Consent Form**

**IRB Project #:**

**Title of Project:** The Influence of Vestibular-Ocular Reflex Training on Static and Dynamic Postural Stability in Subjects with Chronic Ankle Instability

**Principal Investigator:**

Jessica Hilgendorf, ATC, LAT Rod A. Harter, PhD, ATC

Graduate Student Researcher Professor of Athletic Training

113 A EndZone Complex Department of Health and Human Performance

San Marcos, TX 78666 A 132 Jowers Center

[Jh1808@txstate.edu](mailto:Jh1808@txstate.edu) San Marcos, TX 78666

512-618-2141 [rod.harter@txstate.edu](mailto:rod.harter@txstate.edu)

512-245-2972

**Purpose of the Study:**

The purpose of this study will be to compare the long-term effects of two lower extremity rehabilitation protocols against a control condition on the ability to improve postural stability in subjects with chronic ankle instability, as measured by computerized dynamic posturography tests.

**Procedures to be Followed:**

After completing a university approved consent form for participation, you will be tested to ensure that you meet the inclusion criteria and have no exclusion characteristics. You will be asked to complete a form with some basic personal and health information questions. These questions will ask you about your physical activity, injury history, and current state of health. You will also be asked to fill out a form called the Foot and Ankle Ability Measure (FAAM). These forms will help in determining if you are eligible to participate in this study.

Once eligible to participate you will be required to perform four baseline tests on machines located in Jowers Center and in the Health Professions building. When baseline testing is complete you will enter into a four week rehabilitation program. You will be required to come in three times a week and be prepared to participate in a 20-30 minute rehabilitation protocol. You will be required to perform three different tasks during the individual sessions, and both limbs will be used. After the four week program is over you will once again perform the original four tests. With participation you are guaranteed a home rehabilitation program and an elastic resistance band (Theraband™) to help assist you in the exercises.

**Discomforts and Risks:**

There are few minor risks or possible discomforts associated with this study. There is a minute chance that you may lose balance during the testing and fall. You may also experience some pain and/or some minor swelling in your ankle. If at any time you feel uncomfortable during the exercises, please do not hesitate to let me know and we will discontinue testing. You may withdraw with no fear of repercussions.

**Benefits:**

By participating in this study you will receive a take home ankle rehabilitation program and an elastic resistance band (Theraband™) to help yourself improve your level of function. The exercises you will be performing are highly likely to help you improve your daily functional level.

**Duration/Time:**

Your participation in this study will consist of 12 total rehabilitation sessions over a four week period. Each session will last than 30 minutes and the sessions will be held in the EndZone Complex.

**Statement of Confidentiality:**

Your participation in this study is completely confidential. Only the principal investigators will have access to your personal identifiers and to any information that may be linked with your identity. All information that you complete will have an identification number rather than your name to ensure your confidentiality. All data will be stored in a locked cabinet in the Athletic Training Research Lab for seven years. In the event of this study being published, none of your personal identifying information will be disclosed.

**Right to Ask Questions:**

You may ask questions about the research procedures at any time during the course of your participation and you will receive immediate responses. If you have any further questions, please direct these to Jessica Hilgendorf at [jh1808@txstate.edu](mailto:jh1808@txstate.edu) or 512-618-2141 or Dr. Rod Harter at [rod.harter@txstate.edu](mailto:rod.harter@txstate.edu) or 512-245-2972.

**Voluntary Participation:**

Your participation in this study is completely voluntary. You may withdraw from this study at any time. No negative consequences from anyone associated with the study. Please notify Jessica Hilgendorf of your intent to withdraw from the study at any time.

**Request for Further Information:**

Please discuss or express any concerns or questions regarding this study with the investigators at any time. You should feel confident and secure about your involvement in this study. You may also contact the IRB chairperson Dr. Jon Lasser at 512-245-3413.

**Compensation Statement:**

All participants in this study including those who withdraw will be given an at-home rehabilitation program and an elastic resistance band (Theraband™) for use with the home based rehabilitation program.

**Medical Treatment:**

Please be advised that medical treatment is available upon the event of physical injury resulting from this study. Medical treatment will be limited to first aid and ice. In the event that you sustain a more serious injury that requires treatment beyond that, you will need to seek appropriate medical attention. Texas State University students may choose to go to the Student Health Center free of charge (512-245-2167). The investigators will report any adverse events per institutional policy. In the event that you believe you have suffered injury not apparent immediately after testing, please contact the IRB chairperson Dr. Jon Lasser at 512-245-3413, who will review the matter with you and identify any other resources that may be available to you.

**Disclosure and Funding:**

The researcher has no financial or other potential conflict of interest in performing this project. Summary findings will be provided to the participants upon request.

**Approval:**

You have been given an opportunity to ask any questions that you may have and all have been satisfactorily answered.

You must be 18 years of age or older to consent to this study. If you consent to participate in this study and to the above stated terms, please sign your name and date below.

You will be given a copy of this consent form for your records.

Participant Name (Please Print in All Caps)

Participant Signature Date

I, the undersigned, verify that the above informed consent procedure has been followed.

Investigator Signature Date