



Combined Consent and Authorization to Participate in a Research Study

KEY INFORMATION FOR THE EFFECT OF LOAD BEARING AND RECOVERY ON SHOULDER FUNCTION

We are inviting you to take part in a research study about the effects of heavy loads on shoulder function. Healthy individuals, age 18 to 30 who pass a fitness screening are eligible to participate.

WHAT IS THE PURPOSE, PROCEDURES, AND DURATION OF THIS STUDY?

By doing this study, we hope to learn more about how nerves react to wearing a heavy backpack while walking. Before taking part, we will ask you some questions about your health and perform a brief fitness screening. The exercises you will do as part of the fitness screening are listed in Appendix E. Only those individuals who pass the health and fitness screenings will qualify to be in the study. If you qualify and agree to participate, you will walk at medium speed on a treadmill for 1 hour with a 45-pound backpack. While on the treadmill, a trained medical professional will perform nerve conduction studies (NCS). NCS is used to evaluate how fast the nerves send electrical signals. The full NCS procedure is described in the Detailed Consent. Your participation in this research will last about three hours. We hope the results of this study will help us learn how to prevent shoulder injuries caused from carrying heavy loads.

WHAT ARE REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

The study will not include a direct benefit to you. However, some participants appreciate knowing they have contributed to research that may benefit others in the future. You can withdraw from the study at any time. If you experience pain or feel bad during the study, you may stop. Trained medical professionals will perform the screening and the tests. For a complete description of potential benefits, refer to the Detailed Consent that follows.

WHAT ARE REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

With the nerve conduction studies, you may feel a quick, burning pain, and a twitching of your muscles. Some people describe the feeling as similar to the static electricity shock that happens when you walk on carpet and then touch a metal object. Walking on the treadmill may make you feel tired or sore. There is a possibility that the backpack, which weighs 45 pounds, could cause more intense muscle strain during the 1-hour exercise. For a complete description of risks, refer to the Detailed Consent that follows.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of this study is _____, M.D. of the University of Kentucky, Department of _____. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is:

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact staff in the University of Kentucky (UK) Office of Research Integrity (ORI), Monday – Friday, between the business hours of 8am and 5pm EST, at 859-257-9428 or toll free at 1-866-400-9428.

Continue to the Detailed Consent