

INFORMED CONSENT FORM

TITLE OF THE STUDY: The Accuracy of Pedometers in Children

PURPOSE OF THE STUDY

Your child is invited to take part in a research study. The purpose is to compare commonly used step counters (pedometers) in children while they wear them during a typical day.

EXCLUSION CRITERIA

Your child should not volunteer for this study if he/she has difficulty walking and/or needs a cane or other assistive device when walking.

PROCEDURES TO BE FOLLOWED

Your child will meet with the researcher for approximately 20 minutes. Your child should wear light-weight clothing, similar to a physical education class. During this time, your child's standing height, seated height, and weight will be measured. Shoes must be removed for these measurements. You and your child will then be instructed how to properly wear three step counters. One step counter will be attached to the pants on each hip in line with the thigh. The third step counter will be attached to the ankle. Your child will be asked to wear all step counters simultaneously over a 24-hour period. The step counters are to be removed while bathing, sleeping, or playing in sports that could damage the step counters (e.g., football). An instruction sheet will be provided detailing the position of the step counters. If you have any problems or questions please call the phone number listed below. I will call you at the end of the testing day.

You will send the step counters and instruction paper back to me using the box that I give you. After I receive the step counters and the instruction paper in the mail, I will send 2 movie passes in the mail.

POTENTIAL RISKS OF PARTICIPATION

This research study involves minimal risk to the children since we are simply monitoring physical activity. Height and weight will be measured which could be embarrassing for some participants. This will be minimized by providing privacy for these measurements. There is the possibility that unauthorized individuals could access the test results. This risk will be minimized by storing data using subject identification numbers rather than by name, all electronic data will be stored on a password protected computer, and all forms will be stored in a locked cabinet.

POTENTIAL BENEFITS OF PARTICIPATION

As an incentive to participate, your child will receive 2 free movie passes upon return of the step counters and instruction sheet. Otherwise, there is no direct benefit for participating. However, this study will provide researchers and the general public with information on the accuracy of these step counters in children.

CONFIDENTIALITY

Only Brian Tyo and Dixie Thompson, Ph.D., and you will have access to any of your child's information during this research project. The original, signed consent and assent forms

will be kept in a locked cabinet at the University of Tennessee. The results of the study will be published, but your child's name will not be used in any of the material published.

LIABILITY

There will be no payment for treatments or injury resulting from participation in this study.

RESEARCH RELATED INQUIRIES

Any questions concerning this study may be addressed to the following:

Investigator: Brian Tyo, M.A.

Faculty Advisor: Dixie Thompson, Ph.D

Address: The University of Tennessee
Department of Exercise, Sport, and Leisure Studies
1914 Andy Holt Ave.
Knoxville, TN- 37996

Telephone: 865-974-5910

PARTICIPANT RIGHTS INFORMATION

General questions concerning your rights as a participant in research protocols or questions about research related issues may be addressed to the Institutional Review Board Chairman, East Tennessee Children's Hospital through his secretary at (865) 541-8477 or Brenda Lawson of the Research Compliance Services of the Office of Research at University of Tennessee at (865) 974-3466.

VOLUNTARY PARTICIPATION STATEMENT

Participation in this study is voluntary. There will be no penalty for refusal to participate, and your child may withdraw from the study at any time.

PARENT PERMISSION

I have received a copy of this consent form. By signing this informed consent form, I am indicating that I have read and understood this document. I have been given the opportunity to ask questions. By signing this form I indicate that I agree to allow my child to serve as a participant in this research study.

Parent's Signature

Date

Parent's Printed Name

Investigator's Signature

Date