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INFORMED CONSENT DOCUMENT
Evaluation of Activity Monitors in Adults

Principal Investigator: Greg Welk

This is a research study. Please take your time in deciding if you would like to participate. Please feel free to ask questions at any time.

OVERVIEW

The purpose of this study is to evaluate outcomes from a variety of physical activity monitors. There has been considerable interest (by both researchers and consumers) in the utility of various hip and wrist worn accelerometers for assessing physical activity, as well as devices worn in other locations. However, little is known about how they compare when used by individuals under free living conditions. The purpose of this study is to directly compare multiple monitors and methods for assessing physical activity over the course of a single day.

Participants in the study will be asked to wear a number of different activity monitors at the same time for a 36-hour period. The monitors are all designed for comfort and they will be worn on different locations to minimize burden. The goal of the study is to capture typical behaviors in typical adults so you would not need to alter your normal daily routine in any way. You would also not have to be physically active or change your activity habits in any way for the study. The day the monitoring period ends you will be asked to come back to the lab to return the monitors and complete a brief survey.

A small subsample of participants will be recruited for a supplemental component that would include direct observation of their movements for a 1 hour block during their day of monitoring or during a separate one hour period on a different day, as scheduling allows. This is a very standard method used in physical activity research since it provides the only way to really determine what behaviors are being performed while a person wears the monitor. The direct observation will be used to help assess the validity of the activity monitor outputs of the activities being performed. This is an optional component of the study and you will be able to check a box on the last page to indicate if you may be willing to be observed for a 1 hour block of time (at a location and time period of your choosing). The observation can be stopped at any time for important calls and would certainly not include private time for bathroom breaks. If your plans change or you determine that you don't want to be observed you can cancel this component at any time and continue wearing the monitors without the observation component. Thus, this phase is completely optional and only a few participants are needed.

You are being invited to participate in this study because you are an adult, between the ages of 18 and 80, who is willing to wear multiple monitors for a 36-hour period. You cannot participate in the study if you have metal allergies (particularly, allergies to Nickle) since one of the monitors is known to cause reactions in people with this allergy. You should also not participate in the study if you have any medical conditions or injuries that prevent you from moving about on your own by walking.

DESCRIPTION OF PROCEDURES

If you agree to participate, you will be asked to complete one appointment in the Physical Activity and Health Promotion Lab that will last approximately 15 minutes, as well as complete an enrollment survey prior to this visit. This enrollment survey will consist of this informed consent document, as well as demographic (such as gender, age, ethnicity) and anthropometric measurements (such as height and weight) The enrollment survey is expected to take no more than 15 minutes. Following your monitor wear period, you will also be asked to complete an online recall survey reporting the activities and their duration that you completed the previous day. This recall survey is expected to take no more than 30 minutes. Details on the procedures are provided below.

Pre-Participation: You will be asked to review and provide consent to the study using an online survey platform. Eligibility will be determined using a standard clinical exercise screening tool called the **Physical Activity Readiness Questionnaire (PAR-Q).** This instrument includes 7 simple yes/no questions that help to determine if a participant can safely participate in a physical activity intervention.

- **Demographic Survey:** The form will collect basic demographic information such as gender, age and race and contact information. It will also include questions about potential medical issues that may influence eligibility in the study.

If you are eligible, you will be asked to schedule an appointment to complete the following measurements and be provided with the monitors to wear.

Lab Visit: This visit will consist of taking anthropometric measurements, as well as providing instruction on how each of the monitors should be worn and reminders about the recall survey to be completed after monitors are worn.

- **Anthropometric Measurements** (height, weight, body fat)**:** The anthropometric measurements will be conducted in a private room and a maximum of two researchers on the project will be present when these measurements are taken. For height measurements, you will be asked to remove your shoes and the measure will then be taken using a standard stadiometer. For weight, you will be asked to take off all heavy clothing items but it isn't necessary to undress into lighter clothing. The measure will be obtained using a standard electronic scale. For the body fat measure, you will be asked to grip the handles of a simple bioelectric impedance analyzer (BIA) while standing barefoot on a metal footplate. This instrument estimates body fat based on the resistance to current flow in the body but you will not feel any current and the device is completely safe.

Physical Activity Monitoring: You will be asked to wear a number of activity monitors (typically 1 on arm, 1 on the leg, 1 on hip, and 4 on wrists (2 on each side). These monitors are designed for safe wear without any additional risk for discomfort or changes to your privacy or data confidentiality. Additional details are provided at the end of this document outlining the possible monitors to be worn and their wear locations. Specific details on monitors to be worn and instructions for safe wear will be provided at the time of your participation.

You will be asked to wear the monitors for a full 36-hour period starting at 6 pm the day you receive your monitors until 6 am two days later. You will also be asked to complete a basic sleep log recording the time you go to bed and sleep each night, as well as when you wake up the morning of your wear period. In the event that you need to take the monitors off for any reason, you will be asked to note the duration and the reason on the provided tracking sheet. If you agree to the supplemental observation component you will be provided with additional instructions and will arrange the best time and place for this observation to take place. The observations will be done in an inobtrusive way and can be discontinued at any time if needed. The main focus is on the wearing of the monitors for the full 36-hours so at the end of this time period you will be able to take off the monitors and these will be returned after your wear period has ended.

Monitor Return: The morning your 36-hour monitoring period ends you will be asked to arrange a time to drop off monitors with the project research staff so that data can be downloaded and the monitors can be cleaned.

Physical Activity Recall Survey: you will be asked to complete a brief survey about the activities you performed during the full day of your wear period. You will receive an email link directing you to a unique survey entry that will allow your reported activities to be linked to the monitor data. The assessment is self-guided and designed to be completed online. The survey will guide you through the full 24 hours of that day and ask you to recall activities from midnight to midnight. You will be asked to select various activities that you performed and the duration and the intensity (Light, Moderate, Vigorous) of each activity.

RISKS

There are always some risks associated with performing physical activity but you do not have to perform any physical activities as part of the study. In general, you should go about your normal routine and only participate in activities if it is something you would ordinarily do in a typical day. The most common risk associated with this type of study is the potential for minor skin irritation due to wearing the monitor attached to the thigh. However, this monitor can be removed during sleep (if desired) and is attached using a hypoallergenic dressing. Therefore significant skin irritation is not anticipated. If significant irritation occurs, you should remove the monitor and contact the PI to determine if there is another attachment method that will be feasible. If another method is not feasible, you may continue your study participation wearing the other monitors.

BENEFITS

If you decide to participate in this study there may be some direct benefit to you in that you will receive information about your health (BMI, body fat %). It is hoped that the information gained in this study will benefit society by providing valuable information about how best to promote physical activity in adults.

COSTS AND COMPENSATION

There are no planned costs for participating in the study. Your participation in this study is voluntary, and you will not be financially compensated.

PARTICIPANT RIGHTS

Your participation in this study is completely voluntary and you may refuse to participate or leave the study at any time. If you decide to not participate in the study or leave the study early, it will not result in any penalty or loss of benefits to which you are otherwise entitled.

For your own safety, your participation will be terminated if during the course of the study you can no longer safely participate in physical activity due to injury or illness.

RESEARCH INJURY

Please tell the researchers if you believe you have any injuries caused by your participation in the study. The researchers may be able to assist you with locating emergency treatment, if appropriate, but you or your insurance company will be responsible for the cost. Eligible Iowa State University students may obtain treatment from the Thielen Student Health Center. By agreeing to participate in the study, you do not give up your right to seek payment if you are harmed as a result of being in this study. However, claims for payment sought from the University will only be paid to the extent permitted by Iowa law, including the Iowa Tort Claims Act (Iowa Code Chapter 669).

CONFIDENTIALITY

Records identifying participants will be kept confidential to the extent permitted by applicable laws and regulations and will not be made publicly available. However, federal government regulatory agencies, Food and Drug Administration (FDA), auditing departments of Iowa State University, and the Institutional Review Board (a committee that reviews and approves human subject research studies) may inspect and/or copy your records for quality assurance and data analysis. These records may contain private information. De-identified data may be shared with other researchers, however private information will not be shared. Information about you collected for this study may also be used for other research studies. We will not ask you for additional permission before sharing the information as described in this section.

To ensure confidentiality to the extent permitted by law, the following measures will be taken:

- You will be assigned a unique identifier code and all the information you provide will be listed under your code. There will be one file linking your name/identity and your study ID that will be accessible only to the research team. Upon completion of the study this key will be destroyed.
- Any hard copy information provided (such as monitor non-wear periods) will be provided under your study ID and will be stored in a secure filing cabinet. This cabinet can only be accessed by the PI and co-investigators.
- Digital information provided (such as surveys and questionnaires, as well as physical activity monitor data) will be provided under your study ID and will be stored on a password-protected server accessible only to the research team.
- The de-identified data will be kept indefinitely and if the results are published, your identity will remain confidential.

- The company that manufactures some of the monitors will have access to your data since data is stored online. However, they will not have access to your identity because coded ID numbers will be used rather than names. Your data would be anonymous to them.
- Video files will be downloaded to password protected server and removed from recording camera. Video observation will only be used for validation purposes, and no video recordings will be shared or presented.

QUESTIONS OR PROBLEMS

You are encouraged to ask questions at any time during this study.

- For further information about the study contact Dr. Greg Welk at 294-3583 (gwelk@iastate.edu)
- If you have any questions about the rights of research subjects or research-related injury, please contact the IRB Administrator, (515) 294-4566, IRB@iastate.edu, or Director, (515) 294-3115, Office for Research Ethics, Iowa State University, Ames, Iowa 50011.

YOUR CONSENT

_____ Please check this box to indicate that you voluntarily agree to participate in this study, that the study has been explained to you, that you have been given the time to read the document, and that your questions have been satisfactorily answered. You may download and save a copy of this document for your records and a hard copy will be available during your lab visit.

Participant's Name _____

Participant e-mail_____ Tel no._____

☐ Please check this box if you are willing to allow a member of the research team to conduct supplemental observation of your normal activity behaviors by coding the type, posture and intensity of activity you perform over a 1 hour time period.

☐ Please check this box if you are willing to allow a member of the research team to videotape portions of time during the observation period.