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**INFORMED CONSENT DOCUMENT**
Evaluation of Activity Monitors in Adults

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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 research- and consumer-based 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. 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 7 different activity monitors at the same time for a 24 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 after the monitoring period you will be asked to come back to the lab to return the monitors and complete a brief survey.

A small subsample of participants (n ~ 10) will be recruited for a supplemental component that would include direct observation of their movements for a 4 hour block during their day of monitoring. 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. 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 4 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 60, who is willing to wear multiple monitors for a 24 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 two appointments (in the Physical Activity and Health Promotion Lab). Each will last approximately 30 minutes. During the first

appointment, you will sign and date the consent form and a copy of the same will be provided to you. Details on the visits are provided below.

**Visit 1:** This visit will last about 30 minutes. It will determine your eligibility to participate in the study and include collection of anthropometric and demographic measures needed to interpret the data (if you are eligible). 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. If you are eligible, you would complete the following measurements and be provided with the monitors to wear for the day.

- **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.

- **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. For the blood pressure measurement, you will be requested to sit quietly and comfortably for 10 minutes prior to having your blood pressure measured with an automated blood pressure cuff.

**Physical Activity Monitoring:** You will be asked to wear 7 activity monitors (1 on arm, 1 on leg, 1 on hip and 4 on wrists (2 on each side). To clarify, a<u>ll</u> participants will wear the Sensewear armband on the upper arm, 3 Actigraph monitors (one on the hip, and one on each wrist) and the ActivPAL on the thigh). In addition, participants will also wear 2 additional watchband-style monitors (one on each wrist). These will be selected in a random way. You will be assigned to wear either two research-grade monitors (Axivity monitor and a Geneactive monitor) or two consumer monitors (a FitBit and a Jawbone monitor). The shape and size of the extra monitors are the same. The variability with the selection of wrist monitors worn will simply allow us to capture data on a larger number of monitors. A summary of the monitors and positions is shown below:

- Core Armband (Arm - R)
- Actigraph (Wrist - R)
- Actigraph (Wrist - L)
- Actigraph (Waist)
- Actival (Thigh)
- Geneactive or Jawbone (Wrist - L)
- Axivity or Fitbit (Wrist - R)

You will be asked to wear the monitors for a full 24 hour period starting at Midnight the day you receive your monitor until Midnight the following day. 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 24 hours so at the end of this time period you will be able to take off the monitors and these will be returned during Visit 2.

**Visit 2.** This visit will last about 30 minutes but it must be scheduled for the day immediately after your 24 hour monitoring period since you will be asked to complete a brief survey about the activities you performed during the day. The online assessment is self-guided but a member of the research team will help you get it started and will help you enter a coded ID that will link your report to the data from the monitors. The research team member will also be available to answer questions during the recall. The survey will guide you through the past 24 hours and ask you to recall activities in 4 distinct 6 hour blocks (Midnight to 6:00 am, 6:00 am-noon, noon - 6:00 pm and 6:00 pm - Midnight). For each block, you will be asked to select various activities that you performed and the duration and the intensity (Light, Moderate, Vigorous) of each one.

## 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 (worn for 2 weeks: at baseline and end of study). 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 %) and also about your activity patterns as assessed with the monitors. 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. If you choose to participate and wear the monitors as directed for the 24 hour period and the follow-up recall, you will receive a $25 check. You will need to complete a form to receive payment. Please know that payments may be subject to tax withholding requirements, which vary depending upon whether you are a legal resident of the U.S. or another country. If required, taxes will be withheld from the payment you receive.

## 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

Emergency treatment of any injuries that may occur as a direct result of participation in this research is available at the Iowa State University Thomas B. Thielen Student Health Center, and/or referred to Mary Greeley Medical Center or another physician or medical facility at the location of the research activity. Compensation for any injuries will be paid if it is determined under the Iowa Tort Claims Act, Chapter 669 Iowa Code. Claims for compensation should be submitted on approved forms to the State Appeals Board and are available from the Iowa State University Office of Risk Management and Insurance.

## 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.

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 only one hard copy with your name/identity and all information (questionnaires, surveys) will be stored in a secure filing cabinet. This cabinet can only be accessed by the PI and co-investigators.
- There will only be one file maintained on a password protected server. This file can only be accessed by the PI and co-investigators.
- 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.

## 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) or Dr. Laura Ellingson at 294-2552 (ellingl@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 Responsible Research, Iowa State University, Ames, Iowa 50011.

**PARTICIPANT SIGNATURE**

Your signature indicates 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 will receive a copy of the written informed consent prior to your participation in the study.

Participant's Name (printed) _____

_____ _____
(Participant's Signature) (Date)

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 4 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.

**INVESTIGATOR STATEMENT**

I certify that the participant has been given adequate time to read and learn about the study and all of their questions have been answered. It is my opinion that the participant understands the purpose, risks, benefits and the procedures that will be followed in this study and has voluntarily agreed to participate.

_____ _____
(Signature of Person Obtaining Informed Consent) (Date)