CONSENT FORM FOR:
A Wireless, Multimode, Artificial Neural Network-Based Physical Activity Monitor Validation Study

This form describes a research project. It has information to help you decide whether or not you wish to participate. Research studies include only people who choose to take part—your participation is completely voluntary. Please discuss any questions you have about the study or about this form with the project staff before deciding to participate.

Who is conducting this study?

This study is being conducted by Dr Greg Welk who is an Associate Professor in the Department of Kinesiology at Iowa State University. Researchers at Arizona State University will also be collaborating on this research project and conducting a similar study in adults.

Why am I invited to participate in this study?

You are being asked to provide your consent for your child to take part in this study. You child is being requested to participate because they are healthy, between the ages of 7-13 years and are capable of performing physical activities. You should not let your child participate in this study if you have any concerns about your child’s ability to perform moderate or vigorous physical activity.

What is the purpose of this study?

The purpose of this study is to determine whether a portable activity monitor (a combined movement sensor and heart rate monitor) can accurately estimate the energy expenditure (i.e. calories burned) of common free living activities. Estimates from the new monitor will be compared to values from a portable metabolic analyzer that accurately assesses energy expenditure.

What will I be asked to do?

If you agree to let your child participate, your child will be asked to make three visits to our research labs (Foraker Building on ISU campus and the Nutrition and Wellness Research Center (NWRC) in the ISU research park). Each visit will take approximately 1-2 hours so the total duration of the experiment will be about 5-6 hours. There are three phases of the experiment and the specific activities performed on visit 2 and 3 of the experiment will vary to some degree depending on what phase your child participates in. A child can only participate in 1 phase. The general structure of the visits is described below in Table 1 and Table 2.

Table 1. Phases of study

<table>
<thead>
<tr>
<th>Day</th>
<th>Phase 1</th>
<th>Phase 2</th>
<th>Phase 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Screening and anthropometry</td>
<td>Screening and anthropometry</td>
<td>Screening and anthropometry</td>
</tr>
<tr>
<td>2</td>
<td>7-activity routine for 5-min each with 1-min break in between</td>
<td>12-activity routine for 5-min each</td>
<td>7-activity routine for 5-min each with 1-min break in between</td>
</tr>
<tr>
<td>3</td>
<td>12-activity routine for 5-min each</td>
<td>12-activity routine for 5-min each</td>
<td>7-activity routine for 5-min each with 1-min break in between</td>
</tr>
<tr>
<td>Visits</td>
<td>Things to do at each visit</td>
<td></td>
<td></td>
</tr>
<tr>
<td>----------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Visit 1: Screening and Anthropometry Visit                           | - The primary purpose of this visit is to review the research protocol and to obtain permission (informed consent) to allow your son/daughter to participate in the project. If consent is obtained, the investigator at the NWRC will talk to your child (with a witness present) and will explain the study and ask your child if he/she also agree to participate.  
  - If you and your child agree to participate, they will complete some preliminary screening tests and anthropometry tests. The screening tests will check that he/she is eligible to participate and that it is safe for them to do so. The anthropometry tests will collect information about body size and body composition.  
    a) Body composition using a BodPod measurement.  
    b) Height and weight will be measured with a stadiometer and a research quality scale, respectively.  
    c) Body circumferences will be measured with a non-elastic measuring tape in order to accurately compute pelvic mass moments of inertia. The measurements include pelvic circumference, anterior-posterior width, and medio-lateral width measurements. |
| (Duration = 1 hour)                                                  |                                                                                                                                                                                                                         |
| Location: ISU campus-Forker building                                 |                                                                                                                                                                                                                         |
|                                                                      |                                                                                                                                                                                                                         |
| Visit 2:                                                             | - Second Location: NWRC, ISU Research Park  
  You child will be fitted with 5 devices:  
  1) Face-mask  
  2) Shoulder harness with tubes  
  3) A heart-rate monitor (a 1-inch thick band worn around the chest)  
  4) Physical activity monitor on one arm (the size of an IPOD)  
  5) Actigraph accelerometer (size of a pager) worn around the waist  
  - You child will either be asked to perform 7 activities from the 7-activity routine list (see table 2) each for 5-min with 1-min break in between each OR 12 activities (4 sedentary + 4 moderate intensity + 4 more vigorous) from the 12-activity routine list (see table 2) depending on the phase in which they were enrolled in (see table 1). You will be informed of the phase your child will be enrolling in before you sign the consent form. |
| (Duration = 2 hours)                                                 |                                                                                                                                                                                                                         |
| Location: NWRC, ISU Research Park                                   |                                                                                                                                                                                                                         |
|                                                                      |                                                                                                                                                                                                                         |
| Visit 3:                                                             | - After at least 24 hours, the second study day will be scheduled. You and your child will be asked back to the exercise laboratory.  
  - You child will be fitted with 5 devices:  
    1) Face-mask  
    2) Shoulder harness with tubes  
    3) A heart-rate monitor (a 1-inch thick band worn around the chest)  
    4) Physical activity monitor on one arm (the size of an IPOD)  
    5) Actigraph accelerometer (size of a pager) worn around the waist  
  - You child will either be asked to perform 7 activities from the 7-activity routine list (see table 2) each for 5-min with 1-min break in between each OR 12 activities (4 sedentary + 4 moderate intensity + 4 more vigorous) from the 12-activity routine list (see table 2) depending on the phase in which they were enrolled in (see table 1). |
| (Duration = 2 hours)                                                 |                                                                                                                                                                                                                         |
| Location: NWRC, ISU Research Park                                   |                                                                                                                                                                                                                         |
Table 2. 7-activity and 12-activity routines

<table>
<thead>
<tr>
<th>7-activity routine</th>
<th>12-activity routine (4 from each category)</th>
</tr>
</thead>
<tbody>
<tr>
<td>▪ Arm swings while standing still</td>
<td>Sedentary</td>
</tr>
<tr>
<td>▪ Walking on level grade</td>
<td>▪ Sitting quietly in a chair</td>
</tr>
<tr>
<td>▪ Arm swings while walking on level grade</td>
<td>▪ Sitting in a chair reading</td>
</tr>
<tr>
<td>▪ Walking with a back-pack</td>
<td>▪ Watching TV</td>
</tr>
<tr>
<td>▪ Walking up a grade (5% elevation) on a treadmill</td>
<td>▪ Playing a computer game</td>
</tr>
<tr>
<td>▪ Walking up a grade (5% elevation) on a treadmill</td>
<td>▪ Playing a video game</td>
</tr>
<tr>
<td>▪ Loading &amp; unloading boxes</td>
<td>▪ Walking very slowly</td>
</tr>
<tr>
<td>▪ Walking up a grade (5% elevation) on a treadmill</td>
<td>▪ Sedentary</td>
</tr>
<tr>
<td>▪ Loading &amp; unloading boxes</td>
<td>▪ Moderate intensity</td>
</tr>
<tr>
<td>▪ Walking with a back-pack</td>
<td>▪ Light calisthenics</td>
</tr>
<tr>
<td>▪ Walking up a grade (5% elevation) on a treadmill</td>
<td>▪ Sweeping</td>
</tr>
<tr>
<td>▪ Walking with a back-pack</td>
<td>▪ Walking at casual pace</td>
</tr>
<tr>
<td>▪ Walking up a grade (5% elevation) on a treadmill</td>
<td>▪ Brisk walking</td>
</tr>
<tr>
<td>▪ Walking with a back-pack</td>
<td>▪ Hand weight exercises</td>
</tr>
<tr>
<td>▪ Walking up a grade (5% elevation) on a treadmill</td>
<td>▪ Shooting baskets with basketball</td>
</tr>
<tr>
<td>▪ Loading &amp; unloading boxes</td>
<td>▪ Walking &amp; stair climbing</td>
</tr>
<tr>
<td>▪ Walking with a back-pack</td>
<td>▪ Stationary cycling at moderate pace</td>
</tr>
<tr>
<td>▪ Walking up a grade (5% elevation) on a treadmill</td>
<td>▪ Walking while dribbling a basketball</td>
</tr>
<tr>
<td>▪ Walking with a back-pack</td>
<td>▪ Soccer, dribbling at slow jogging pace</td>
</tr>
<tr>
<td>▪ Walking up a grade (5% elevation) on a treadmill</td>
<td>▪ Playing catch with a ball</td>
</tr>
<tr>
<td>▪ Loading &amp; unloading boxes</td>
<td>▪ More vigorous</td>
</tr>
</tbody>
</table>

What are the possible risks associated with participation

(a) The monitor being tested in the study presents no risks, but participants may feel slight discomfort from the heart rate monitor strap. Participants will be allowed to discontinue wearing any of the devices at any point during the study if intolerable discomfort occurs.

(b) The metabolic analyzer used to measure energy expenditure poses no risks but participants may feel slight discomfort from wearing the facemask. Participants will be asked to wear the facemask for no longer than what is necessary to obtain an accurate measurement of energy expenditure.

(c) The study involves evaluation of the monitor during physical activity. Performing physical activity poses some risks including muscle soreness, fatigue, dizziness, shortness of breath, injury and death. The activities performed are similar to what children would perform under free living conditions so the risks associated with the experiment are no more significant than activities performed at home. The trials will be directly monitored by trained exercise technicians. The technician will monitor affective responses, heart rate responses and movement characteristics and if anything is irregular, the trial will be stopped. Participants can also choose to stop the trial at any time.

What are the possible benefits associated with participation

While there will be no direct benefit to the participant, it is hoped that this study will benefit society and the scientific community by developing and refining better ways to measure physical activity. From the results, researchers will learn whether the monitor is a viable tool for the measurement of energy expenditure and activity under laboratory conditions simulating activities of daily living.
Will I incur any costs from participating or will I be compensated?

There are no costs for participation, except for the time commitment required to complete the testing. Visit 1 is scheduled to take 1 hour and visits 2 and 3 will likely take about 2 hours so the total time commitment is about 5 hours. Visit 1 is primarily an orientation and screening visit but participants will receive $25 dollars for completing each of the other subsequent visits, in appreciation for your involvement in the study.

How will the information I provide be used?

The information provided/collected from your child will be used to determine the accuracy of the new monitoring device. The data from the different phases of the experiment will serve different purposes. Data collected in the initial phase (1) will be used to improve future versions of the monitor. Data from the subsequent phases will be done to evaluate the accuracy. Results from the project will be summarized in written reports and shared at professional meetings and appropriate peer-reviewed scientific journals.

All the personal, medical and dietary information collected from you will be shredded/destroyed after a period of 5 years or within 1 year of publication (whichever comes first).

What measures will be taken to ensure the confidentiality of the data or to protect my privacy?

Records identifying participants will be kept confidential to the extent allowed by applicable laws and regulations. Records will not be made publicly available. However, federal government regulatory agencies, auditing departments of Iowa State University, the ISU Institutional Review Board (a committee that reviews and approves research studies with human subjects), and researchers at Arizona State University who are collaborating on this project may inspect and/or copy your records for quality assurance and analysis. These records may contain private information. The Food and Drug Administration views this type of monitoring device as a “low-risk medical device” and has some jurisdiction over research of this type. They reserve the right to inspect and/or copy participant’s records.

To ensure confidentiality to the extent allowed by law, the following measures will be taken: your child will be assigned a unique code that will be used on all forms. If the results are published, your child’s identity will remain confidential.

There will be only one hard copy with your child’s name/identity, personal and medical history information which will be stored in a secure filing cabinet at the NWRC. This cabinet can only be accessed by the PI and co-investigators. There will be no online file where your child’s name/identity will be connected directly with their health/exercise information or any other piece of data or information collected from you/your child. Your child will be assigned a unique identifier code and all the information they provide will be listed under their code. There will only be one file maintained on a password protected server, one back-up file on a CD and one hard-copy connecting your child’s name with this unique identifier code. This file can only be accessed by the PI and co-investigators.
What are my rights as a human research participant?

Participating in this study is completely voluntary. You may choose not to permit your child to take part in the study or for them to stop participating at any time, for any reason, without penalty or negative consequences.

Whom can I call if I have 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 515-294-3583 or 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 of Research Assurances, 1138 Pearson Hall, Iowa State University, Ames, Iowa 50011.

Consent and Authorization Provisions

Your signature indicates that you voluntarily agree to allow your child 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.

Child’s Name (printed) ________________________________

Parent/Guardian Name (printed) ________________________________

__________________________________________________________

(Signature of Parent/Guardian or Legally Authorized Representative) (Date)

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 Consent) (Date)
ASSENT FORM TO PARTICIPATE IN A RESEARCH STUDY

What is a research study?

A research study is a way to test new ideas in science. Research studies help doctors and scientists learn new things.

Why are we doing this research study?

We are trying to learn more about physical activity in children. We want to see if machines that count your heart beat and how much your body moves, can correctly tell us about your physical activity.

You are asked to take part in this research study because are 7 years to 13 years old, healthy, and can perform physical activities without any problems.

Who is in charge to the research study?

The doctor in charge of this study at Iowa State University is Dr. Gregory Welk. There are also many other doctors and scientists at Arizona State University and Iowa State University working together on this research study.

Where will the research study be carried out?

This research study will take place at the exercise laboratory at the Nutrition and Wellness Research Center at Iowa State University. You will have to come to the exercise laboratory with your parents on three separate days.

What will happen during the research study?

Visit 1 will be 1 hour long. During this time, we will explain the study to you, ask you some questions about yourself and take some measurements such as your height and weight.

Visit 2 and 3 will be 2 hours long each. On either of the two days that you some to the exercise laboratory,

You will carry out a list of 7 physical activities. Examples of the 7 physical activities are just walking, walking on a slope, swinging your arms when standing and walking with a back-pack.

OR

You will carry out a list of 12 physical activities where 4 will be very easy activities, 4 will be easy to little hard and 4 will be most lively. Examples of

- Very easy activities: Watching TV, sitting quietly in a chair, sitting and reading, playing a video game
- Easy to little hard activities: Sweeping, walking fast, soccer, playing catch with a ball
- Most lively activities: One-on-one basketball, jogging, climbing stairs
You will perform each activity for 5-min only. When you carry out these physical activities, you will be asked to wear several items.

1. A face-mask that fits comfortably over your nose and mouth so that we can measure your breathing (Figure 1).

![Figure 1. Face mask](image)

2. The mask has some tubes that connect to small straps that you wear over your shoulders that fit around your chest (Figure 2).

![Figure 2. Straps around shoulders & chest](image)

3. A black strap around your chest that helps to count your heart beat (Figure 3). These straps will be under your clothes.

![Figure 3. Black strap around the chest](image)

4. A small IPOD-like object on your arm to measure your physical activity (Figure 4).

![Figure 4. Arm band](image)

5. A belt with a small red box that measures how much your body moves. This will also be worn under your clothes.

![Figure 5. Red box with a belt](image)
What are the bad things that can happen from this research?

Sometimes things happen to people in research studies that may hurt them. In this research study you may feel your muscles ache because of the physical activity. Some people may also feel dizzy after physical activity. These injuries are rare.

What are the good things that can happen from this research?

People also may have good things happen to them because they are in research studies. These are called benefits. There are no benefits to you being in this study.

What else should you know about the research?

If you do not want to be in this study, you do not have to participate. Being in this study is up to you and no one will be upset or angry if you do not want to participate or even if you change your mind later and want to stop.

You will receive a $50 gift certificate for completing this research study.

You can ask any questions that you have about the study. If you have a question later that you didn't think of now, you can call me at 515-294-3583 or ask me next time.

- If I have not answered your questions or you do not feel comfortable talking to me about your question, you or your parent can call IRB Administrator, (515) 294-4566, IRB@iastate.edu, or Director, (515) 294-3115, Office of Research Assurances, 1138 Pearson Hall, Iowa State University, Ames, Iowa 50011.

Please ask as many questions as you need to make sure you understand the study before you sign this form.

MINOR'S NAME
(SIGNATURE)
(If age 7 up to 15)

MINOR'S NAME
(PRINT)

DATE

PARENT OR GUARDIAN
(SIGNATURE)

PARENT OR GUARDIAN
(PRINT)

DATE

PERSON OBTAINING ASSENT
(SIGNATURE)

PERSON OBTAINING ASSENT
(PRINT)

DATE