Consent form for participating in a research study

You are being asked to participate in a research study. Researchers are required to provide a consent form to inform you about the research study, to convey that participation is voluntary, to explain the risks and benefits of participation, and to empower you to make an informed decision on whether or not to participate. You should feel free to ask the researchers any questions you may have.

Study title
Validation of several activity tracking devices for estimation of physical activity variables

Purpose of research
You are invited to take part in this research study to help us answer several important questions. We are interested in determining how accurate various activity monitors are for measuring variables such as heart rate, breathing rate, steps, and calories burned.

Inclusion/exclusion criteria
To be eligible to participate in this study, you must be between the ages of 18-65 and be able to perform at least five minutes of activities commonly performed in daily living. Examples of such activities would include sedentary (i.e., lying down, sitting) and ambulatory (i.e., walking, stationary cycling, jogging) activities. At the beginning of the study, you will fill out a Physical Activity Readiness Questionnaire (PAR-Q). If you answer "Yes" to any question on the PAR-Q, you will need written clearance from your medical doctor/physician before being able to participate in the study.

You will not be eligible to participate if 1) you are pregnant, 2) you are wheelchair bound, 3) you have uncontrolled metabolic or cardiovascular disease, or 4) you have a gait abnormality that would invalidate the use of these activity monitors for measurement of activity. We seek to recruit 30-60 individuals to be a part of this study.

Study location and duration
The study will take place in the Human Performance Laboratory at Alma College. Some activities will also be performed in the Stone Recreation Center of Alma College. Your time required for this research study is a single session estimated to be approximately 2 hours.

What you will do (study procedures)
You should avoid consuming food or drinks (other than water) for at least 2 hours prior to arriving at the HPL. Additionally, you should refrain from caffeine, tobacco, medications affecting blood pressure or heart rate, and vigorous exercise for at least 2 hours prior to your scheduled test time. When you arrive at the lab, you may be asked to complete some or all of the following forms:

Demographics form: This form will ask you to report your gender, age, height, weight, and potentially other similar types of demographic information.

Physical activity readiness questionnaire: This questionnaire will ask you to complete seven health-based questions to help us determine if it is safe for you to participate in this study. If you answer "yes" to any, you will need to obtain clearance from your doctor before being able to participate in the study.

Edinburgh handiness inventory: This questionnaire will ask you 10 questions to help us determine which hand is your dominant hand and how strong of a hand dominance you have.

Activity protocol: Following completion of the relevant forms, you will be fitted with four activity monitors (2 GENEActiv monitors, Fitbit Charge HR, and Jawbone UP4) which will measure movement

as well as accelerations of the body as you perform the activities that are a part of the visit. These activity monitors are small in size and light-weight, and they will be placed on your left and right wrists. You will also be wearing a pedometer and a Hexoskin. The pedometer will be placed on your right hip and will measure the amount of steps taken during each activity. The Hexoskin is a skin-tight tank top you will wear throughout testing, and this measures heart rate, breathing rate, calories burned, and steps taken. The Parvomedics (metabolic measurement system) will be used to measure your breathing rate and the amount of calories burned during an exercise. The Parvomedics will require you to wear a headpiece with a mouthpiece attached, and you will also have to wear nose clips to assure that you are only breathing in and out of your mouth. You will be able to breathe freely in and out of the mouthpiece.

Once fitted with this equipment, you will be asked to complete a variety of activities that many people preform commonly in everyday life. The activities you will perform will fall into one of two categories: a) Sedentary and b) Ambulatory. Sedentary activities are those involving minimal movement, including lying down, sitting, and standing. Ambulatory activities are those used for locomotion, including walking (leisure, moderate, and brisk), walking on an inclined grade (leisure and moderate), stationary cycling, and jogging. There are a total of 15 activities/exercises. Each activity will be performed for 5-6 minutes, with 1-2 minutes of rest between activities. Upon completion of the activities, we will help you remove all your equipment before you leave the lab.

Researchers will be present to assist you if you have any questions during the activities. The total time expected for the visit is approximately 2 hours.

Possible risks and discomforts
We foresee no risks being associated with wearing physical activity monitors or a pedometer, other than slight skin irritation that may occur if the monitors are worn too tightly. If you feel that a monitor is too tight, please inform the research staff and we will loosen it for you. We also foresee no risk in taking measures of height, weight, and other variables such as heart rate and breathing rate.

There are no risks known to be associated with wearing the Parvomedics mouthpiece and headpiece. However, you may experience slight jaw discomfort from wearing the mouthpiece for a long period of time. This discomfort is will minimized because you can remove the mouthpiece at any time between activities if you start to feel uncomfortable.

There are also no risks known to be associated with wearing the Hexoskin. However, you may experience discomfort from the tank top itself due to the tight fitting design of the Hexoskin. The tank top fits tightly because this allows the sensors to be in direct contact with the skin producing the most accurate results.

The movement involved with physical activity could lead to some acute or delayed discomfort, mainly due to muscle and joint soreness and/or strains. However, these risks are no greater than those experienced in everyday life as all of activities you will perform are common activities performed in daily living. You will perform most of these activities at your own pace, which will reduce the likelihood of any muscle or joint soreness or injury.

Possible study benefits
Benefits of this study include information regarding your current height, weight, and witnessing how your heart rate, breathing rate, caloric expenditure, and steps taken change with the different activities/exercises performed.

Voluntary participation
Your participation in this study is completely voluntary and you are free to withdraw your permission at any time, for any reason, without penalty or prejudice from the investigator and/or research assistants.

You will not be treated differently if at any time you wish to withdraw from the study. Please feel free to ask any questions of the investigator and/or research assistants before signing this form and at any time during the study. You will receive a copy of this consent form to take with you.

Confidentiality of information
We will keep confidential all research records that identify you to the extent allowed by law. Your information will be combined with information from other people taking part in the study, so there will be no way of identifying your data once the study is complete. When we write about the study to share it with other researchers, we will write about the combined information we have gathered.

We will keep informed consent forms and data for a minimum of three years after the project closes, and we will retain deidentified data indefinitely. Data collected will be kept confidential and stored in locked filing cabinets in the Alma College Human Performance Laboratory and/or on password-protected computers in the lab. However, by signing this form you allow the research investigators to make your records available to the Institutional Review Board (IRB) Offices at Alma College and regulatory agencies as required by law. All data obtained from this study will be used for research purposes only, not for the diagnosis of any disorder.

In the event of a negative experience
If you believe you are hurt or if you get sick because of something that is done during the study, you should contact *John Smith, the study's principal investigator, at (989) 555-5555*, immediately. Emergency medical treatment is available if you become injured or ill during your participation in this research project. It is important for you to understand that Alma College will not pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study, nor for any lost wages, disability, pain or discomfort, unless required by law to do so. You should ask your insurer if you have questions about your insurer's willingness to pay under these circumstances.

Therefore, the costs related to your care and treatment because of something that is done during this study will be your responsibility. You will be responsible for the costs of any medical care that is provided. It is understood that in the unlikely event of an injury or illness of any kind as a result of your participation in this research project that Alma College, its agents, and employees will assume whatever responsibility is required by law.

Contact information
Before you decide to accept this invitation to take part in the study, please ask any questions that might come to mind now. Later, if you have questions about the study such as scientific issues, how to do any part of the study, or to report an injury, please contact the study's principal investigator, *John Smith, at (989) 555-5555 or email at smith1111@example.edu*.

For questions or concerns about your rights as a research subject, how to obtain information or offer input, or to register a complaint about this study, you may contact (anonymously if you wish) Dr. Alex Montoye, the chair of the IRB, at montoyeah@alma.edu. You will be given a copy of this consent form to take with you.

Documentation of Informed Consent

I have read the above information about the research study titled **Validation of several activity tracking devices for estimation of physical activity variables** and have been given an opportunity to ask questions. I agree to participate in this study and I have been given a copy of this consent document for my own records.

_____ _____

Participant signature (or legal representative) Date

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Participant name (or legal representative) printed

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Signature research staff