**Date:** **Valid for Use Through:**

**Study Title:** Calibrating free-living physical activity characteristics across functionally-limited populations using machine-learned accelerometer approaches

**Principal Investigator:** Edward Melanson, Ph.D.

**Study Coordinator:** Mallory Boyd. MS.

**COMIRB No:** 16-2706

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You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

## Why is this study being done?

You are being asked to be in this research study because this study plans to develop equations to measure physical activity using activity monitors in people with movement limitations.

Regular physical activity is known to have positive effects on many health outcomes. In research, physical activity is often measured using activity monitors worn on the hip, wrist or ankle. These instruments determine how much physical activity a person does based on the amount of movement the person does. This is done with equations that use the data collected by the activity monitors. However, these equations are usually developed using measurements on healthy people. People who have movement disorders related to diseases such as Parkinson's and Multiple Sclerosis, or conditions such as knee replacement, stroke, or arthritis have very different movement patterns than people without these diseases. Thus, the equations used to convert activity monitor data will not work well in people with these diseases or conditions. The purpose of this study is to develop equations to measure physical activity using activity monitors in people with movement limitations. Rather than creating specific equations for each individual disease and condition, we will perform simple tests to measure upper and lower body function, and then group people into different clusters based on these tests. Our preliminary studies show that these equations are more accurate than equations based on specific diseases or conditions.

## Other People in the Study

Up to 106 people from the Denver area will participate in this study.

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## What happens if I join this study?

If you agree to participate in this study, you will be asked to complete an initial screening visit followed by two study visits. During the screening visit, you will be asked to perform some tests to measure your physical function.

During the first study visit, we will measure your resting metabolic rate and body composition using a method called dual x-ray absorptiometry (DXA). This visit may be combined with your screening visit.

During the second study visit, you will be asked to schedule a 12-hour stay in a room calorimeter. This room will measure your energy expenditure (how many calories your body burns) over 12 hours. While in the room, you will also wear activity monitors on your hip, wrist, and thigh. You will be asked to perform several activities and exercises.

All testing and procedures will be completed on the Anschutz Medical Campus in Aurora at the University of Colorado Hospital and Clinical Translational Research Center (CTRC).

This research study is expected to take approximately 4 years. Your individual participation in the project will take ~1-2 months.

## Summary of testing schedule and procedures

Screening visit (Approximately 2 hours): During the initial visit, called the screening visit, you will

- Review the **consent form** with a member of the research team. The consent process may also be done remotely through Zoom (phone or video option)
- Complete a **medical history** form. Participants will also be given the option to complete the medical history form remotely online after the consent process.
- Have a **physical examination** with the study doctor.

If the study doctor approves you for participating in the study, you will then be asked to perform several functional tests. This is done so we can group participants into different functional categories

- *Grip strength*: We will measure your grip strength using an instrument called a dynamometer. You will be asked squeeze the dynamometer by gripping it in one hand. You will perform one practice trial and then three measured trials with at least 15 seconds rest between each trial. The task will be repeated with both hands.
- *Gait speed:* We will determine your usual self-selected walking and maximum walking speed over 10 meters (~30 feet) as you walk down a non-carpeted hallway.
- *Physical performance test:* You will be asked to perform the following tasks, and we will score you on how long it takes you to complete each task.
    - Balance with 2 feet on the ground

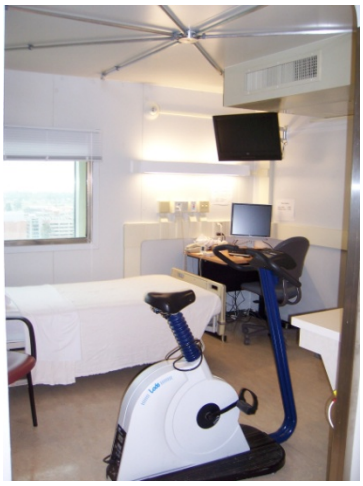
- Lift a book onto a shelf
- Put on and remove a jacket
- Pick up a penny from the floor
- Rise from a chair
- Turn 360 degrees
- Walk 50 feet
- Climb one flight of stairs
- Climb stairs (maximum of 4 flights)

Study visit #1 (approximately 2 hours) – During this visit, we will perform tests to measure your resting metabolic rate and body composition.

- *Resting metabolic rate* - After lying still on your back for 30 min, we will place a plastic hood over your face and head. We will then measure the air you breathe for approximately 20 minutes. This will allow us to measure how many calories your body burns at rest.

- *Body composition* – We will measure your body composition (i.e. how much fat and muscle you have) using a **dual x-ray absorptiometry (DXA)**. You will be asked to lie on a table and the DXA scanner will scan over your body. The procedure lasts about 15 minutes. Women of child bearing age will take a urine pregnancy test prior to the DXA scan.

Study visit #2 (12 hours) – You will be asked to stay in the metabolic room (calorimeter) which is located in the Clinical Translational Research Center (CTRC) on the 12th floor of the Anschutz Inpatient Pavilion at the University of Colorado Hospital. The metabolic room is sealed, but fresh air is constantly drawn in. The room is 12 feet by 12 feet and contains a regular hospital bed, a desk, a toilet, a telephone, a flat screen TV with a DVD player, and a computer with internet access. The TV has basic cable TV access (i.e. news and sports channels, some entertainment channels). The room also has wireless internet access, so you can bring your own laptop. There are curtains over the windows so that you may have privacy. The room is also equipped with a closed-circuit camera that can be viewed in the control room and at the nursing station. However, the control for the camera is located inside the room, and you can turn the camera off anytime you want privacy, for example, when going to the bathroom. Temperature inside the calorimeter will be maintained at 72°F (22°C).



Prior to entering the room, we will secure activity monitors to your hip, wrist, and ankle using an elastic belt and Velcro straps. You will also secure a thin rectangular activity monitor to the midline of your thigh using a hypoallergenic adhesive. You will enter the room at 8 AM, and exit the room at 8 PM the same day. You will be served breakfast, lunch, and dinner around 8:30 AM, 1 PM, and 6 PM on day 1 and 2. You will order your meals through the Hospital Room Service. You can also drink water and other beverages at any time of the day.

During the 12-hr calorimeter stay, you will be asked to complete a variety of different exercises and activities. You can do these activities and exercise whenever you want and for how long you want. We will provide you a check list to follow to be sure that you do all of the prescribed activities. An example list of activities is provided below:

- **Sedentary behaviors**: Reading, writing, watching television, card/board games.
- **Household tasks**: Sweeping the floor, dusting, vacuuming, cleaning windows.
- **Occupational tasks**: Computer work, moving items.
- **Transportation**: Treadmill walking at different speeds, less than normal pace, normal pace, and faster than normal pace.
- **Leisure**: Walking/running/cycling, light calisthenics, light resistance dumbbells, yoga, tai chi. Some of these activities can be performed by following along a pre-recorded video (e.g. calisthenics, dumbbells, yoga, tai chi).

During the stay in the room calorimeter, we will video record you during the day so we have a record of when you did the different activities. The video recordings will be stored and sent for analysis at the University of Wisconsin Milwaukee.

**What are the possible discomforts or risks?**

Any procedure has possible risks and discomforts. The procedures in this study may cause all, some, or none of the risks or side effects listed. Rare, unknown, or unforeseeable (unexpected) risks also may occur.

Discomforts you may experience while in this study include the following

*Risk of radiation exposure:* You will be exposed to radiation during the DXA scan. During each DXA you will be exposed to a small amount of radiation. This amount of radiation is about 1% of the dose received during a standard chest x-ray. Your natural environment has some radiation in it. This DXA will give you about the same amount of radiation that you would get from your environment in 2 days.

*Risks of video recording*: There is a risk of loss of privacy because of the video recordings. Video recordings will be saved be using a specific ID (no personal information will be included). Video files will be sent over a secure network connection to the University of Wisconsin and all precautions will be taken to ensure files are transferred safely. All video recordings will be maintained on password protected files. No audio will be collected on the video recordings.

*Risk of staying in the metabolic room:* Some people may feel claustrophobic in the metabolic room. However, the room is large and comfortable, and has a large picture window that lets in natural light. You will not be locked in the room; the door can be opened from the inside. There is also a call button and telephone that connects the metabolic room directly to the nursing station. We will also provide you with a call button to wear around your neck in case you need immediate assistance and cannot reach a call

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button. However, if you leave the testing room early, the testing session is over. If you have a caregiver who you would like to stay with you during your time in the metabolic room, you may bring them along for your study visit. Your caregiver will be allowed to stay just outside of the metabolic room. You will be able to talk with on the telephone provided in the room and see them through a window while you are completing your visit.

*Risks of wearing activity monitors:* During the stay in the metabolic room, you will be asked to wear activity monitors on your wrist, hip and thigh. The adhesive or straps used to secure some of the devices may cause a slight skin irritation, but this is rare. Devices worn on the hip or wrist are not expected to cause any skin irritation.

*Risks of Resting Metabolic Rate (RMR) measurement:* There are no known risks to this procedure. You may however feel claustrophobic when the ventilated hood is placed over your head. The hood is clear plexiglass and will be removed immediately if you begin to feel claustrophobic.

*Risks of interviews and questionnaires:* The interviews, questionnaires, and collection of medical information may cause you to feel embarrassment or a loss of privacy. If we discover you have signs of depression or feelings of suicide, we will refer you to the University of Colorado Depression Center and/or we will get you immediate help.

*Performance tests –* There are no know risks of performing the performance tests.

There is a risk that people outside of the research team will see your research information. We will do all we can to protect your information, but it cannot be guaranteed.

The study may include risks that are unknown or unforeseeable or unexpected at this time.

Risks of the usual care you receive are not risks of the research and are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

**What are the possible benefits of the study?**

This study is designed to learn more about a cost-effective device used to measure total daily energy expenditure. This study is not designed to treat any illness or to improve your health. Also, there may be risks, as discussed in the section describing the discomforts or risks.

**Who is paying for this study?**

This research is being supported by a grant from the National Institutes of Health.

**Will I be paid for being in the study?**

You will be paid up to $125 for participating in this study. You will receive $25 for the screening visit, $25 if you complete study visit #1 (RMR and DXA), and $75 if you complete study visit #2 (the room calorimeter study). *You are responsible for arranging transportation for your study visits; however, the study site (through the Sponsor) may reimburse you for travel expenses if you must travel >60 miles (roundtrip) to attend study visits. Rates of reimbursement will be provided as agreed upon by the institution and study sponsor (for standard mileage reimbursement rates, see:* https://www.cu.edu/psc-procedural-statement-travel)

If you leave the study early, or if we have to take you out of the study, you will be paid only for the visits you have completed.

It is important to know that payments for participation in a study are taxable income. Your SSN will be collected and used to report this taxable income to the IRS.

**Will I have to pay for anything?**

It will not cost you anything to be in the study.

**Is my participation voluntary?**

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled. If there are any new findings during the study that may affect whether you want to continue to take part, you will be told about them.

**Can I be removed from this study?**

The study doctor or the investigators may decide to stop your participation without your permission if they think that being in the study may cause you harm, or for any other reason. Also, the sponsor may stop the study at any time.

**What happens if I am injured or hurt during the study?**

If you have an injury while you are in this study, you should call Edward Melanson, Ph.D., Principle Investigator of the study, immediately. His phone number is (303) 724-0935. You can also contact the study Doctor, Vicki Catenacci, M.D., at 303-315-7424. We will arrange to get you medical care if you have an injury that is caused by this research. However, you or your insurance company will have to pay for that care.

**Who do I call if I have questions?**

The researcher carrying out this study is Edward Melanson, Ph.D. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call Edward Melanson at (303) 724-0935. You will be given a copy of this form to keep.

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While your primary source of information pertaining to participation in this study is the principal investigator, Dr. Melanson, a Research Subject Advocate is also available on the CTRC at (720) 848-6662 to answer questions relating to participation in this study.

If you have questions regarding your rights as someone in this study, you can call Dr. Melanson. You can also call the Colorado Multiple Institutional Review Board (COMIRB) office at (303) 724-1055

**Who will see my research information?**

The University of Colorado Denver and the hospital(s) it works with have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include:

- University of Colorado Denver
- University of Colorado Hospital
- University of Wisconsin-Milwaukee

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the University of Colorado Denver and its affiliate hospitals may not be covered by this promise.

We will do everything we can to keep your records a secret. It cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Primary Investigator, at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

All data collected during this study will be transferred via a secure network connection to the University of Wisconsin. We will take all precautions to ensure files are transferred safely.

**Edward Melanson, Ph.D.**
Division of Endocrinology, Metabolism, and Diabetes
12801 East 17th Ave, RC1 South RM 7103, MS 8106

 Initials_____

Aurora, CO 80045

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information.

- Federal offices such as the Food and Drug Administration (FDA) that protect research subjects like you.
- People at the Colorado Multiple Institutional Review Board (COMIRB)
- The study doctor and his/her team of researchers.
- The National Institutes of Health, who is paying for this research study.
- Officials at the institution where the research is being conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research
- We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

You have the right to request access to your personal health information from the Investigator.

**I**nformation about you that will be seen, collected, used and disclosed in this study:

- Demographic Information (age, sex, ethnicity, address, phone number, etc.
- Research Visit and Research Test records

**What happens to data that are collected in this study?**

The data collected from you during this study are important to this study and to future research. If you join this study:

- Both the investigators and any sponsor of this research may study your data.
- If data are in a form that identifies you, UCD or the hospitals involved in this study may use them for future research only with your consent or IRB approval.
- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

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1. **Re-contact.** Please indicate whether you would like to hear about future studies being conducted by our research group. If 'Yes' is checked, then you will be asked to sign a separate consent form for the Recruitment Database protocol 17-0949.

   ☐ Yes ☐ No _____Initials

**HIPAA Authorization for Optional Additional Study Procedures**

In this form, you were given the option to agree to additional, optional research procedures, interested in hearing about future studies being conducted by our research group. You must also give us your permission, under HIPAA rules, to use and disclose the information collected from these optional procedures, as described above.

If you decline to give us permission to use and disclose your information, you cannot take part in these optional procedures, but you can still participate in the main study. Please initial next to your choice:

_____ I give permission for my information, from the optional procedures I have agreed to above, to be used and disclosed as described in this section.

_____ I **do not** give permission for my information for any optional procedures to be used and disclosed; I understand that I will not participate in any optional procedures.

## Agreement to be in this study

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

Signature:_____ Date:_____

Print Name:_____

Consent form explained by:_____ Date:_____

Witness Signature: _____ Date_____

Witness Print Name: _____