UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Sedentary Behaviors and Physical Activity in University IT Workers
Principal Investigator: [Sungwon Park, PhD, RN; Assistant Professor/ Postdoctoral Fellow, School of Nursing/Michigan Society of Fellows 2022-2025, University of Michigan (UM)]
Co-Investigators: [Janet Larson, PhD, RN; Professor at the UM School of Nursing, Weiyun Chen, PhD; Associate Professor and Director of the Physical Activity and Health Laboratory at the UM School of Kinesiology; Marie-Anne Rosemberg, PhD, RN; Assistant Professor at the UM School of Nursing; Philip Veliz, PhD; Research Associate Professor at the UM School of Nursing]

You are invited to take part in a research study. This form contains information that will help you decide whether to join the study.

1.1 Key Information

Things you should know:

- The purpose of the proposed study is to understand sedentary behaviors (SB) and physical activity (PA) in UM IT workers, identify factors influencing SB and PA at the individual, interpersonal, and organizational–environmental levels, and determine the potential relationship between metabolic syndrome, SB, and PA. Through this study, we will be able to understand how different types and levels of activity, such as walking, standing, and sitting for long periods of time, affect the health of IT workers. The study will also help us understand how the movement patterns of IT workers are related to the risk of developing metabolic syndrome, which is a collection of conditions that can lead to long-term problems like heart disease and type 2 diabetes.
- If you choose to participate, you will be asked to schedule a 1-hour appointment to complete the survey and measure your weight, height, waist circumference, and blood pressure in the PI's private offices. In addition, you will be asked to wear two accelerometer devices on your first visit and maintain a daily log for 1 week. After this 1 week, you will be asked to have your blood drawn to test for metabolic syndrome at the Labcorp clinic in Ann Arbor, close to the UM central campus. Once you complete all the above study requirements, you will be asked to meet the research team in the PI's private offices to return the devices, receive your metabolic syndrome test results, and be compensated for your time. The whole study procedure will take approximately 9–10 days.
- Risks or discomforts from the proposed study are mild discomfort when answering survey questions and attaching the accelerometer data devices (activPAL and ActiGraph). To minimize discomfort related to the survey, the PI will conduct it in a private office and in a caring, supportive manner. When attaching the devices, skin barrier protection wipes and skin adhesive remover wipes will be used to protect the skin. When drawing blood, there will be a small

risk of some pain when the needle is inserted and of bruising and/or infection at the site. To minimize this risk, the research team will ensure that blood is drawn in a professional manner and will regularly check for adverse events. A potential risk is a breach of confidentiality by either members of the research team or employees of Labcorp. However, the use of de-identified information, strict ethical standards, and limited access to participant information will minimize this risk. In addition, a final potential risk is a breach of confidentiality by external malevolent actors, such as hackers. To minimize this risk, all participant data will be stored securely in the UM REDCap system and Dropbox folders at UM, with access limited largely to the PI.

- The direct benefits of your participation will be awareness of your health status related to metabolic syndrome as you will be given the test results directly (i.e., how many risk factors of metabolic syndrome you have).
- Taking part in this research project is voluntary. You do not have to participate and you can stop at any time. Please take time to read this entire form and ask questions before deciding whether to take part in this research project.

2. PURPOSE OF THIS STUDY

In the proposed study, we use accelerometer devices to expand our understanding of sedentary behaviors and physical activity among a group of highly sedentary workers. We have four specific aims: (1) establish different ways to measure sedentary behavior and physical activity in UM IT workers for 24 h; (2) classify IT workers into groups based on activity level, and examine whether certain groups and job tasks are linked to the lowest and highest sedentary behavior and physical activity during working hours; (3) identify factors influencing sedentary behavior and physical activity; and (4) determine risk factors affecting the relationship between metabolic syndrome, sedentary behavior, and physical activity.

3. WHO CAN PARTICIPATE IN THE STUDY

3.1 Who can take part in this study? You will be eligible to participate in the study if you (1) are affiliated with the UM IT department; (2) can speak and comprehend English; (3) are willing to give a voluntary blood sample; and (4) are willing to wear the activPAL and ActiGraph devices for 1 week. You are NOT eligible to participate if you have (1) known skin sensitivity or allergic reaction to tape (3M Tegaderm Transparent Film); (2) any disease or injury that limits physical activity; (3) a compromised immune system (e.g., current or past chemotherapy/radiation within the past 12 months); (4) any skin conditions on your lower extremities (e.g., skin rash, blisters, or skin breakdown on your legs); (5) blood disorders (e.g., anemia, hemophilia), or (6) pregnancy, which can potentially change your movement patterns.

3.2 How many people are expected to take part in this study? We estimate up to 79 participants.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

After verifying your eligibility to participate through the eligibility screening test and filling out the e-consent form, the research team will schedule a 1-hour appointment with you. During this 1 hour, you will be asked questions for a survey and asked to wear two devices. For the survey, you will first be assigned a unique ID number to protect your identity and maintain confidentiality. The survey questions will be asked by the PI at her private offices on campus (School of Nursing building or Rackham graduate building, depending on your preference). You will be asked to respond to study-specific questionnaires on the UM REDCap system using a laptop computer provided by us. The research team will also ask you open-ended questions and enter your answers on UM REDCap. We will measure your height, weight, body mass index, and waist circumference. Our survey will not include sensitive information that identifies you. However, some questions designed to understand your sedentary behavior and physical activity may cause some discomfort. If you feel discomfort with any question, you can stop the survey at any time.

Once the survey is done, you will be told how to wear the accelerometers and complete the daily logs. You will be given time to ask questions and will receive reminders to fill the daily logs via text message for 1 week. After wearing the devices for 1 week (after day 7), we will ask you to detach both devices and report to Labcorp to give your blood samples under fasting conditions. To verify that you are involved in our study, we will give you a confirmation paper copy with your study ID number and computer generated, randomized ID number (these will protect your actual identity). Labcorp will match your information with what we have already provided them and then draw a blood sample from you. You will get the test results after all the study requirements are completed.

We will ask to meet you once more to return the devices and collect your daily logs. On that day, you will receive an electronic Amazon gift card worth $60 to compensate you for your time.

None of the above procedures are experimental. All of the methods, i.e., the survey, wearing the devices, and blood test, are well-tested standard methods.

4.2 How much of my time will be needed to take part in this study? You will be asked to take a one-time, 1-hour survey, have your height, weight, body mass index, and waist circumference measured, and wear two devices. The devices will have to be worn for seven consecutive days, during which time you will also be asked to maintain daily logs. After detaching the devices, you will be asked to go to a Labcorp clinic once, under fasting conditions to have your blood drawn. Finally, you will be asked to meet us to the return devices, learn your test results, and be compensation, which is estimated to last less than 15 minutes. Overall, this study will last 9-10 days.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

- The anticipated risks to participants in this study are minimal. The major risks will be the loss of privacy and confidentiality. In addition, there will be a small risk of pain, bruising, and/or infection at the site of needle insertion when having your blood drawn. To minimize this risk, your blood will be drawn using aseptic techniques performed by advanced healthcare providers at the Labcorp clinic. You can inform the PI, who is a registered nurse, of any concerns or side-effects at any time. During the survey, the PI will check whether you experienced any side-effects as a result of having your blood drawn (e.g., fainting).
- There will be a small risk of mild discomfort when answering questions about your sedentary behavior and physical activity. To minimize this discomfort, the PI will conduct the survey in a private office and in a caring, supportive manner. The PI is a registered nurse with a doctoral degree and is experienced in asking for and receiving sensitive information. Your responses will be kept completely confidential, and no one other than the research team will have access to this information. All data will be stored in UM platforms that comply with HIPAA laws, regulations, and other applicable policies. Additionally, you may skip questions, stop the survey, or drop out of the study whenever you wish to do so.
- There will be a small risk of experiencing skin irritation or discomfort when you wear the accelerometer devices (i.e., ActiGraph and activPAL). The research team will use skin barrier protection wipes and skin adhesive remover wipes to protect your skin when applying and detaching the activPAL device. The team will also use light Tegaderm tape when applying the device to minimize discomfort. Potential adverse reactions to the tape are skin irritation, rashes, blisters, excessive redness, and bleeding. If an adverse reaction happens, must remove the device immediately and can contact the PI any time (24/7).
- If any unanticipated problems arise during recruitment or data collection, the PI will promptly report the issue to the senior mentor (Dr. Larson) and the department head as soon as the PI becomes aware of the problem. The PI also will report any appropriate problems to the IRB within 24 hours, as warranted.

5.2 How could I benefit if I take part in this study? How could others benefit?

You will receive a free metabolic syndrome test (worth $25) and know the result by the end of the study. You will therefore know your health status related to metabolic syndrome (i.e., how many risk factors of metabolic syndrome you have). In addition, others may benefit from the knowledge gained from this study. For instance, occupational health nurses, employers, and researchers who provide care for workers and help minimize sedentary lifestyles at work will learn more about how to provide better care. The findings will also highlight the potential relationship between metabolic syndrome, sedentary behavior, and physical activity. Thus, this study will help IT workers like yourself improve their health by increasing physical activity and reducing sedentary behavior.

5.2.1 Will the researchers provide information to me about what they learn from analyzing my blood sample and biometric measures related to metabolic syndrome? We may learn things about your health as part of the proposed research. Your metabolic syndrome test results and the meanings of the biometric values will be shared with you. We will use the definition established by the National Cholesterol Education Program-Adult Treatment Panel III guidelines, which state that metabolic syndrome is present if three or more of five criteria are met: (1) waist circumference > 40 in (men) or 35 in (women); (2) blood pressure > 130/85 mmHg; (3) fasting triglyceride level > 150 mg/dL; (4) fasting high-density lipoprotein cholesterol level < 40 mg/dL (men) or 50 mg/dL (women); and (5) fasting blood glucose level > 110 mg/dL. The study team/study will not cover the costs of any follow-up consultations or actions.

6. ENDING THE STUDY

6.1 If I want to stop participating in the study, what should I do?
You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 9 “Contact Information”. If you choose to tell the researchers why you are leaving the study, your reasons may be kept as part of the study record. The researchers will keep the information and metabolic syndrome test results collected about you for the research unless you ask us to remove the information from our records and destroy the metabolic syndrome test results. If the researchers have already used your information in a research analysis, it will not be possible to remove your information.

7. FINANCIAL INFORMATION

7.1 Will I be paid or given anything for taking part in this study? You will receive an electronic Amazon gift card worth $60 and a free metabolic syndrome test worth $25 when you complete participation in the study. However, if you withdraw from the study after completing the survey but before wearing the accelerometer devices, then you will not be compensated. We will also not compensate you if wear only one of the two devices. If you wear both devices for less than a week, then we will give you direct monetary compensation for the number of days you have worn the device ($60 divided by 7 is about $8.5, so for each day you will receive $8.5). If you withdraw from the study after wearing the devices for 1 week but before conducting the blood test, you will still receive the full compensation of the $60 gift card. Please note that we will not cover the cost of travel from the UM campus to the Labcorp clinic.

8. PROTECTING AND SHARING RESEARCH INFORMATION AND METABOLIC SYNDROME TEST RESULT

8.1 How will the researchers protect my information? All data collected will be kept secure and strictly confidential at all times. No identifying information about you will be stored before you sign the e-consent form. For the survey, you will first be assigned a unique ID number to protect your identity and maintain confidentiality. All information related to the survey will be stored securely using UM REDCap at the PI's personal

office on the UM campus to ensure privacy. CrowdStrike and Microsoft Defender antivirus software have been installed in the laptop to be used for the study. The campus network is behind a firewall, in addition to which the laptop has its own specific firewall. The survey questions will be stored on the UM REDCap system. The list connecting participant names, telephone numbers, and email addresses will be kept securely in a Dropbox folder at UM. The list will be used when the PI sends text messages or emails as reminders, such as to check the accelerometer devices and regularly fill the daily logs. Only the PI will be allowed to access the list. For the metabolic syndrome test, deidentified information in the form of your study ID number and computer generated, randomized ID number will be shared with Labcorp (a test clinic company). You will verify yourself to Labcorp as a study participant using a confirmation paper copy that we will provide.

8.2 Who will have access to my research records?
There are reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- University, government officials, study sponsors or funders, auditors, and/or the Institutional Review Board (IRB) may need the information to make sure that the study is done in a safe and proper manner.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

8.3 What will happen to the information and metabolic syndrome test results collected in this study? We will keep the information and metabolic syndrome test results we collect about you during the research, such as information we learn from analyzing your blood test, height, weight, body mass index, and waist circumference. Your name and other information that can directly identify you will be stored securely (UM REDCap and Dropbox folder at UM) and will be deleted all as soon as our study is completed (by 2024). The results of this study may be published as an article or presentation, but will not include any information that will let others know who you are.

8.4 Will my information and metabolic syndrome test results be used for future research or shared with others? Yes, we will use the de-identified results for future research or sharing with others because these preliminary findings will form a foundation for larger studies on IT workers with metabolic syndrome outside UM.

9. CONTACT INFORMATION

Who can I contact about this study?
Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Sungwon Park, PhD, RN
Email: sungwonp@umich.edu
Phone: (734) 707-1616

If you have questions about your rights as a research participant, or wish to obtain information, ask questions or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

University of Michigan
Health Sciences and Behavioral Sciences Institutional Review Board (IRB-HSBS)
2800 Plymouth Road
Building 520, Room 2144
Ann Arbor, MI 48109-2800
Telephone: 734-936-0933 or toll free (866) 936-0933
Fax: 734-936-1852
E-mail: irbhsbs@umich.edu

You can also contact the University of Michigan Compliance Hotline at 1-866-990-0111.

10. YOUR CONSENT

Consent to Participate in the Research Study

By signing this document, you are agreeing to be in this study. Make sure you understand what the study is about before you sign. I will give you a copy of this document for your records and I will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information in Section 9 provided above.

I understand what the study is about and my questions so far have been answered. I agree to take part in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____