

**UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY**

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Lower-limb Prosthetic Control for Stumble Recovery during Locomotion

Principal Investigator: Ram Vasudevan, PhD, Department of Mechanical Engineering, University of Michigan

Co-Investigator(s): Elliott Rouse, PhD, Department of Mechanical Engineering, University of Michigan

Study Sponsor: National Science Foundation

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 study is to determine how able-bodied individuals respond to perturbations (such as tripping over an obstacle) while walking, develop robotic lower-limb prosthesis behavior to imitate these responses, and test whether the prosthesis behavior is effective.
- If you choose to participate, you will be asked to attend two separate experiments at the Ford Robotics Building, University of Michigan North Campus, Ann Arbor, MI. In the first experiment, you will walk on a treadmill while a type of perturbation (trip or cable-pull) is applied to you. The second part of the study is a separate session on a different day that will be scheduled after the first is completed. In the second part, you will do the same thing, but while wearing a robotic knee-ankle prosthesis via an able-bodied adaptor. After the second part of the study, you will be asked to fill out a brief (less than 10 minutes) survey about your experience. The two experiments will be separated by 1-12 months, depending on the availability of scheduling. Each testing visit will be no more than 6 hours.
- Risks or discomforts from this research include a rare risk of falls, rare risk of a breach of confidentiality, infrequent risk of a stubbed toe or sprained ankle, infrequent risk of skin irritation, and likely risk of fatigue.
- There are no direct benefits of your participation.

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

This study aims to both increase understanding of human stumble-recovery behaviors and implement a stumble-recovery controller on a robotic knee-ankle prosthesis. Developing stumble-recovery controllers in robotic lower-limb prostheses is of interest because amputee falls lead to a higher rate of injury and a negative impact on daily activities. Currently, however,

most robotic prostheses do not have stumble-recovery features. A robotic prosthesis that could identify and execute the common stumble-recovery strategies could help provide a more natural and intuitive recovery. Therefore, this research study is being conducted to examine (1) how able-bodied individuals recover from trips/perturbations, and (2) whether a knee-ankle prosthesis controller designed to mimic these behaviors can lead to a successful recovery.

3. WHO CAN PARTICIPATE IN THE STUDY

3.1 Who can take part in this study? Healthy, able-bodied individuals between the ages of 18-50 may participate in this study. All participants must be in general good health and able to walk in the community without using an assistive device such as a cane or walker. Participants must not have had an injury or surgery to the pelvis, legs, or ankles in the past 6 months and no past major lower-limb surgeries that affect stamina or pain level. The subject must have normal or corrected-to-normal hearing and vision. They must be able to read and understand English.

Subjects will not be eligible if they meet any of the following criteria:

- Inactive, or physically unfit to walk for 60 minutes continuously
- Unable to read and understand English
- Diagnosed with a neurological disease such as Parkinson's disease, multiple sclerosis, stroke, ataxia, etc.).
- Diagnosed with a condition (e.g., diabetes, certain autoimmune diseases, certain viral or bacterial infections, certain inherited disorders, or other diseases), or taking certain medications, especially those used to treat cancer, that may cause peripheral neuropathy (damage to nerves outside of the central nervous system, such as the hands and feet).
- Ongoing balance issues, such as dizziness, fainting or diagnosed balance disorder.
- History of vertigo or diagnosed balance disorder.
- Doctor or health care provider told individual to limit the amount/type of exercise to do.
- Experience chest pain when exercising.
- Cognitive deficits or visual/hearing impairment that would impair their ability to give informed consent and follow simple instructions during the experiment.

In addition, the following criteria will exclude individuals from becoming eligible for the study:

- Adults unable to consent.
- Individuals who are not yet adults (infants, children, teenagers).
- Pregnant individuals.*
- Prisoners

*Individuals who self-report a pregnancy will be excluded from the study because they walk and balance differently than individuals who are not pregnant. If an individual was to participate while being unknowingly pregnant, there are no additional risks to the individual or fetus.

3.2 How many people are expected to take part in this study? 40 subjects are expected to take part in this study over the course of three years.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

The goal of this study is to understand how able-bodied individuals respond to trips, and whether a novel prosthesis control method can assist in a successful trip recovery. The study consists of two parts, described below. Each study subject will participate in both parts of the study. Today, you will be asked to complete the protocol for the first study part.

For all participants in this study, when you arrive for your first study visit (at Neurobionics Lab, Room 1140, of the Ford Robotics Building), a qualified researcher will explain the study to you. The researcher will leave the room as you read this form, but will be available nearby for you to ask questions. If you are eligible and agree to participate after any questions are answered, you will then sign this form. The researcher will then ask you for your basic information (such as your age) and take measurements of your current weight and height.

The experiment will take place in the same room (Neurobionics Lab, Room 1140, of the Ford Robotics Building).

For the first part of the study, you will change into spandex-material clothes (in a private room) with reflective markers for motion tracking. An experienced researcher will attach additional reflective markers on your skin once you have changed into the clothes. Additionally, the research team will use inertial measurement units (IMUs) to collect additional kinematic information. The IMUs will be attached to you via a band around the arm/leg or medical grade tape. Next, an experienced researcher will fit you with a safety harness. While you stand in the middle of the treadmill, the safety harness will be lowered from the ceiling until it is at appropriate height for you, then a member of the study team will help you buckle the harness and adjust strap lengths until you are comfortable. You will only undergo one type of perturbation during this study, although there are three options. Below are the three types of perturbations, and any hardware that may need to be attached:

1. A tripping perturbation using a retractable tether attached to both feet from behind. The tether will pass through a braking device, meant to interrupt the forward motion of the swing foot. In each tether trip perturbation, the brake will be applied for either 150, 250, or 350 ms, decided randomly during the experiment. When not activated, the tethers should have minimal impact on your walking gait.
2. A tripping perturbation created by a block released at the top of the treadmill, to either the right or left feet (but not both feet at the same time). This type of perturbation provides the opportunity for physical tripping obstacles. If the block perturbation is used for your experiment, you will wear "dribble goggles" (goggles that restrict the lower field of view; commonly used by basketball players learning to dribble) to minimize your anticipation of the blocks. You will also be instructed to avoid looking down at the treadmill during the experiment. Furthermore, as this type of perturbation involves your

toe hitting a physical obstacle, the study team will decide if additional padding must be added to your shoes to minimize the risk of toe pain and add layers of cotton if necessary.

3. A lateral cable-pull perturbation system, designed to apply sideways forces to your approximate center of mass (the hip area) while walking.

The study team member who is running the experiment will tell you which option of the three will be used for your experiment. If option 1 will be used, the study team member will attach tethers to each of your feet. This fitting process includes adjusting the tether system so that it does not interfere with your normal walking. If option 2 will be used, the study team member will give you a pair of dribble goggles to wear, instruct you to avoid looking down at the treadmill during the experiment, and add layers of cotton padding to the toe of your shoes if necessary. If option 3 will be used, the study team member will attach a hip harness, which will have cables on either side that will be used to apply lateral forces. The cable-pull harness will not interfere with the safety harness' efficacy. This fitting process involves adjusting the hip harness system so that the harness straps are secure and comfortable and provide minimal interference to walking. You will then walk on a treadmill and occasionally be subject to perturbations. The study team will engage you in conversation during the experiment to reduce the chance of you anticipating the perturbations and reacting in advance. You will not be subject to more than one type of perturbation during the study.

The exact protocol for Experiment 1 is as follows:

1. Before the experiment begins, you will be assigned a perturbation type: tripping via tethers, tripping via block perturbations, or lateral cable-pull perturbations. The perturbation type will rotate between subjects in order that Experiment 1 is scheduled.
2. Once you have consented, your age, height, and weight will be recorded.
3. For the collection of kinematic and kinetic data, you will change into clothes with reflective markers. You will be given a private room to change, and can notify the study team members when you are done. The study team will place additional reflective markers on your skin. Furthermore, the research team will attach IMUs for collecting kinematic data via a band around a limb or medical grade tape.
4. You will be fit with a safety harness in case of falls.
5. If the tether perturbation trials are being used, you will be fitted with tethers on each foot. If the block perturbations will be used, the study team will first evaluate whether your toes need additional protection and add a layer of cotton on the toes if needed. Next, you will put on dribble goggles to restrict your lower field of vision. Third, the study team will instruct you to avoid looking down at the treadmill throughout the experiment. If the lateral perturbations are being used, you will be fit with the cable-pull perturbation system.
6. You will be asked to walk naturally on the treadmill at a chosen speed for 5 minutes.
7. The perturbed trials will then commence. You will walk for under 60 minutes, with around 30-100 perturbed walking trials interspersed with 5-15 unperturbed walking trials in randomized order. The perturbations will be induced by either (1) the tether on

either foot, (2) the block perturbations, or (3) the lateral cable-pull perturbations. There will be at least 10 seconds between perturbations. If the tether perturbations are being used, the tether will be braked for 150, 250, or 350 ms, decided by a random number generator for each perturbation. You will not be asked to perform any more than 60 minutes of continuous walking. You will also not be asked to walk for a total time greater than two hours for a single session. Optional breaks will be structured into the testing trials, but you may request a break between trials at any time.

8. You will be instructed to inform researchers about any pain or discomfort during the perturbed walking trials, and will be asked throughout the study if you are comfortable as well as monitored for signs of discomfort.

The second part of the study is a separate session on a different day that will be scheduled after the first is completed. For the second part of the study, you will be fitted with the safety harness again, as well as an able-bodied adaptor that is connected to the knee-ankle robotic prosthesis. An experienced researcher will fit you into the able-bodied adaptor, ensuring a secure and comfortable fit. Then, depending on the type of perturbation that was used in the first part of the study (option 1, 2, or 3), the researcher will:

1. Attach the tether to the prosthetic foot,
2. Instruct you to wear dribble goggles and avoid looking down at the treadmill, or
3. Fit the cable-pull hip harness system to you.

The robotic prosthesis used in the second part of this study can be programmed so that the knee and ankle will assist during stumble recovery using small motors. This device is very safe and will never move your legs into an unsafe position.

Once again, you will walk on the treadmill while the perturbations are applied. You will not be subject to more than one type of perturbation. This time, however, there will be three distinct stages, testing three types of prosthesis controllers in randomized order. These three controllers will all respond to perturbations differently. In between the stages, you will have the option to take a break.

The exact protocol for Experiment 2 is as follows:

1. The perturbation type will be determined based on which perturbation type was used in your Experiment 1.
2. For the collection of kinematic and kinetic data, you will change into clothes with reflective markers. You will be given a private room to change, and can notify the study team members when you are done. The study team will place additional reflective markers on your skin. Furthermore, the research team will attach IMUs for collecting kinematic data via a band around a limb or medical grade tape.
3. You will be fit to a harness in case of falls.
4. You will be fitted with the able-bodied adaptor and the knee-ankle prosthesis on your left leg.

5. For the tether perturbation trials, tethers will be fit to the leg with the knee-ankle prosthesis. If the block perturbations will be used, the study team will put on dribble goggles to restrict your lower field of vision. Next, the study team will instruct you to avoid looking down at the treadmill throughout the experiment. You will not need to add padding to your shoes in this part, because the blocks will only be released on the side with the knee-ankle prosthesis. If the lateral perturbations are being used, you will be fit with the cable-pull perturbation system.
6. You will be asked to walk naturally on the treadmill at a chosen speed for 10 minutes. If you feel comfortable walking with the knee-ankle prosthesis and adaptor before the 10 minutes are up, you can request for the experiment to begin.
7. The order for testing the three prosthesis recovery methods will be determined using a random number generator.
8. The perturbed trials will now commence, divided into three parts with three different test controllers. Only one type of perturbation (tripping due to tether, tripping due to block, or lateral cable-pulls) will be used across all parts. In each part, you will walk for under 25 minutes, with around 30-50 perturbed walking trials interspersed with about 5 unperturbed walking trials in randomized order. There will be at least 10 seconds between perturbations. If the tether perturbations are being used, the tether will be braked for 150, 250, or 350 ms, decided by a random number generator for each perturbation. In each 25-minute segment, only one type of controller will be used. In between each of the three parts, you will have the option for a break. You can request as much time for a break as needed. You will also not be asked to walk for a total time greater than two hours for a single session. You may request a break between trials at any time.
9. You will be instructed to inform researchers about any pain or discomfort during the perturbed walking trials when wearing the knee-ankle prosthesis and adaptor, and will be asked throughout the study if you are comfortable as well as monitored for signs of discomfort.
10. After the perturbation system, harness, and reflective markers are removed, you will be asked to fill out a short questionnaire about their experience during the perturbed trials while wearing the knee-ankle prosthesis (e.g., comfort, balance). This questionnaire will be a paper-and-pencil survey. The study team will leave the room while you fill out the questionnaire to maintain subject privacy.

In both Experiments 1 and 2, you will have different wireless sensors placed on your body to measure your movements. These sensors include: 1) small, lightweight, reflective markers that are attached to your skin or clothing using medical-grade tape and are used to record information about your movements, 2) small, lightweight devices called Inertial Measurement Units (IMUs) to record information about your movements.

For all study parts, you may be videotaped or photographed while you perform the study tasks (only if you have consented below with a signature in **Section 11**). Researchers will let you know if and when you will be videotaped or photographed. No video or photographs will be taken

without your knowledge and permission. These files will be kept in a secure location and only used by the study team.

The following data will be collected during the study:

1. Height, weight, gender, shoe size.
2. Kinematic and kinetic data during gait (e.g., joint angles, torques, and powers), which will be captured via motion capture technology, IMUs, and force plates.
3. Data collected from the knee-ankle prosthesis itself, including ankle joint angle, velocity, and acceleration, device linear acceleration and angular velocity, motor current and voltage, and load cell data.
4. The forces applied during tether or cable-pull perturbations, if applicable.
5. Walking speed.
6. Subjective data (e.g., comfort, balance). These data will be obtained through a paper-and-pencil questionnaire immediately following the experiment.

We would also like your permission to keep your recorded data collected in the main study so that we may study it in future research. The future research may be similar to this study or may be completely different. You can take part in the main study even if you decide not to let us keep your data for future research.

Future use of your de-identified data will be conducted in compliance with applicable regulatory requirements. You will not find out the results of future research on your data. Allowing us to do future research on your data will not benefit you directly. Your identifiable private information will be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

4.2 How much of my time will be needed to take part in this study? Your participation will include 2 separate visits, spaced 1-12 months apart, at a maximum of 6 hours each for a total of 12 potential hours of participation.

4.2.1 When will my participation in the study be over? The entire study is expected to last 3 years. Your participation in the study will end after your second study visit.

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?

1. There is a risk of falls (rare). The risk of falls can stem from two parts of this study: the perturbation (retractable tether, block release, or lateral cable-pull), and wearing the knee-ankle prosthesis. The retractable tether, block release, and lateral cable-pull perturbations are designed to cause slight disturbance, not falls, but could still cause you to lose balance. Experiment 2 involves a robotic knee-ankle prosthetic device. Since

you may not be used to walking with this device and the able-bodied adaptor, and it may initially impact your balance in addition to the perturbations. If the block perturbations are used during your experiment, you will wear goggles to restrict your lower field of vision and be instructed not to look down at the treadmill, which may make balance more difficult. You will wear a safety harness and will also have handrails on either side of the treadmill. The harness is a commercial body weight support system that is routinely used in clinics and hospitals to safely support body weight during gait training and reduce the risk of falls in a range of patient populations; including elderly, Spinal Cord Injured (SCI) subjects, and others with severe gait deficits. The harness system has not been, nor will it be modified, from its original design, and will be used as shipped from the manufacturer. Additionally, you will be monitored throughout the study to ensure you are able to maintain balance appropriately. An experimenter will monitor your location on the treadmill, warn you if you approach the treadmill's edge, and use an emergency stop button for the treadmill if necessary. If the knee-ankle prosthesis controller malfunctions, the motor has built-in safety limits that immediately power the device off. The harness and handrails should be sufficient to prevent falls in this case as well.

2. Risk of sprained ankle or stubbed toe (infrequent). You are expected to successfully recover from the induced stumbles/perturbations, but you may sprain your ankle or stub your toe while walking on the treadmill. If the block perturbations are used during your experiment, you will wear goggles to restrict their lower field of vision and be instructed not to look down at the treadmill, which may also affect balance and lead to a sprained ankle or stubbed toe. You will be provided with time to accommodate walking on a treadmill in order to minimize the risk of injury. The timing of the tether/cable/block perturbations will be chosen based on previous research to cause trips, perturbations, and stumbles that you should be able to recover from.
3. Toe pain from block perturbations (infrequent). This risk is only for block perturbations. It is expected that you will hit your toe on the blocks, and there is a risk of toe pain from hitting these physical obstacles. Every effort will be made to minimize this risk, including designing the blocks to minimize impact force, instructing you to wear closed-toed shoes with adequate toe protection, and adding a layer of cotton to the toes of your shoe if deemed necessary.
4. Skin irritation or discomfort from the able-bodied adaptor (infrequent). Experienced research team members following manufacturer recommendations will fit the adaptor to you. You will have ample opportunity to discuss the fit and comfort of the adaptor, and you will be monitored for sign of discomfort.
5. Skin irritation due to the tape or band used to attach sensors or reflective markers (infrequent). All sensors and reflective markers will be affixed to you using medical grade tape. Any redness or irritation is temporary and should go away shortly after the tape is removed, making this a minor risk.
6. Muscle soreness (infrequent). The duration of the testing period will be minimized to avoid muscle soreness. Minor discomfort is normal, but you should notify the experimenters if they experience prolonged or severe muscle or joint soreness.

7. Fatigue or exhaustion (likely). You will be allowed to take breaks if you become tired at any point in the study. Additionally, there are breaks built-in to the study protocol between individual trials to minimize exhaustion.
8. Breach of confidentiality (rare). Because this study collects information about you, one of the risks of this research is a loss of confidentiality. All data will be confidential and kept in a locked cabinet or on a secure server that only the study team has access to. You will be assigned a code for data collection. Data will be stored under this code as an identifier for reference. The code assignment will be kept separate from data information. Six months after both experiments are complete for a subject, we will delete the subject name-code key. If you consent to photos/videos during the experiment, these will be encrypted and kept in a different folder on the secure server and not associated with the subject code. The study team will blur all faces in images/videos before associating them with a coded subject. Six months after each experiment, all faces in the photos/videos will be removed or blurred, or else the photos/videos will be deleted. See Section 8 of this document for more information on how the study team will protect your confidentiality and privacy. Lastly, you can skip questions in the survey for any reason, such as if you are not comfortable with a question or unsure about the answer.

As with any research study, there may be additional risks that are unknown or unexpected.

5.1.1 What happens if I get hurt, become sick, or have other problems because of this research? The researchers have taken steps to minimize the risks of this study. Please tell the researchers if you have any injuries or problems related to your participation in the study. The University may be able to assist you with obtaining emergency treatment, if appropriate, but you or your insurance company will be responsible for the cost. By signing this form, you do not give up your right to seek payment if you are harmed because of being in this study.

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

You will not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study.

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. 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 collected about you for the research unless you ask us to delete it from our records. If the researchers have already used your information in a research analysis it will not be possible to remove your information.

You may be withdrawn from this study if you are uncomfortable with the induced perturbations, it is determined that you are not able to comfortably walk with the device, or for missing scheduled research visits.

If you are withdrawn from the study after data has been collected, the collected data will be retained if it is deemed to be scientifically relevant by the researchers (i.e., if it can still help researchers answer the questions raised in Section 2 of this consent document). If the data is not relevant, it will be discarded.

7. FINANCIAL INFORMATION

7.1 Will I be paid or given anything for taking part in this study? You will receive \$20/hour for your participation in the study, which will be paid by a check sent to the address you provide. If there are any partial hours of participation, compensation will be rounded to the nearest half hour. If you leave the study early, you will be compensated for the hours you participated.

Because this study pays more than \$100, the University of Michigan will collect and safely store your name, address, social security number, and payment amount for tax reporting purposes. If you receive more than \$600 in payments in a calendar year, this information will be sent to the Internal Revenue Service (IRS) for tax reporting purposes and an extra tax form (Form 1099) will be sent to your home. If you are a University of Michigan employee, your research payments are tracked separately and are not included as part of your payroll.

7.1.1 Will I need to pay anything to be part of the study? To be part of the study, you will need to pay for the cost of travel to the study site.

7.2 Who could profit or financially benefit from the study results?

There are no financial conflicts of interest to disclose. This research can lead to new discoveries, such as new prosthesis controllers. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

8. PROTECTING AND SHARING RESEARCH INFORMATION

8.1 How will the researchers protect my information?

All data collected from you will be held in confidence; you will be assigned a confidential code and no identifying personal data will be stored with study data. Study data will be stored in password protected servers or in locked filing cabinets as applicable. All recorded data will be stored on a password-protected server for further offline analysis. Your name/subject code link will be stored in a locked file cabinet. Six months after both experiments are complete for a subject, we will delete the subject name-code key. In the event that the results of this data are published, you will be referenced through the subject code and your identity will not be indicated.

If you give specific permission on the consent, you may be photographed and videotaped during the experiment for possible use in scientific presentations or publications. All photographs and videos will be stored separately from your de-identified data until faces are removed/blurred. All photographs and videos will be stored in an encrypted folder on a password-protected server in a locked room. If you consent to use of images/video in scientific presentations or publication, every effort will be made to protect your privacy in these images, but they may include a blurred face or other identifying features.

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.
- If you receive any payments of \$100 or more for taking part in this study, the University of Michigan accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.

8.3 What will happen to the information collected in this study?

We will keep the information we collect about you during the research for future research projects. The data from both experiments may be useful in future projects involving walking stability, human motor control, lower-limb prosthesis control, or for other purposes unrelated to this study. Your name and other information that can directly identify you will be stored securely and separately from the research information we collected from you, and the identified information will be deleted or de-identified in 6 months following Experiment 2.

Six months after both experiments are complete, we will delete your name from the subject key. Within six months after each experiment is complete, we will either blur faces or delete images/videos from that experiment that contain identifying information.

The results of this study could be published in an article or presentation, but will not include any information that would let others know who you are.

Study results from the experiments you took part in will not be shared directly with you.

8.4 Will my information be used for future research or shared with others?

We may use or share your research information for future research studies. If we share your information with other researchers it will be de-identified, which means that it will not contain your name or other information that can directly identify you. This research may be similar to this study or completely different. We will not ask for your additional informed consent for these studies.

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: Ram Vasudevan

Email: ramv@umich.edu

Phone: 1-734-647-5560

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 1169Ann Arbor, MI 48109-2800
Telephone: 734-936-0933 or toll free (866) 936-0933
Fax: 734-936-1852
E-mail: irbhsbs@umich.edu

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. We will give you a copy of this document for your records and we 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): _____

11. OPTIONAL CONSENT

Consent to use video recordings/photography for purposes of this research. The faces will be blurred in the video recordings/photography within 6 months of the experiment in which they were recorded.

This study involves video recordings/photography. The faces in the video recordings/photographs will be blurred within 6 months of the experiment in which they were recorded. If you do not agree to be video recorded/photographed, you can still take part in the study.

_____ Yes, I agree to be video recorded/photographed

_____ No, I do not agree to be video recorded/photographed.

Print Legal Name: _____

Signature: _____

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

Consent to use of video recordings or photographs with blurred faces for publications, presentations or for educational purposes.

I give permission for video recordings/photographs made of me as part the research to be used in publications, presentations or for educational purposes. The faces in the video recordings/photographs will be blurred if they are used in publications, presentations or for educational purposes.

_____ Yes

_____ No

Print Legal Name: _____

Signature: _____

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