Official Title: Enhancing Voluntary Motion in Broad Patient Populations With Modular Powered Orthoses

NCT number: NCT05240014

Document Date: May 11, 2026

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INSTRUCTIONS FOR EDITING THIS DOCUMENT

1. Turn on Track Changes.
2. Make necessary changes in consent, and update the footer intended for study team version control.
3. Upload the revised consent into Section 10-1, maintaining the IRBMED standard naming convention as follows:
   - **Consent - Tracked**
   - **Consent -** *Concise Subtitle* **– Tracked** (provide a subtitle when there are multiple consents associated with the study)
   - **Assent - Tracked**
   - **Parental Permission/Assent - Tracked**
   - **Parental Permission – Tracked**

NOTES:
Words identified above in bold must not be changed; words identified in italics may be modified by the study team. Informed consent subtitles should be a one or two word descriptor, such as**:** **Consent – *Genetic* – Tracked** or **Consent – *Blood Draw* - Tracked**.

Each subsequent track changes version should be stacked on the previously uploaded track changes version.

DO NOT delete any documents or stacks of documents from eResearch; these are retained for historical and regulatory reference purposes.

DO NOT upload a clean version of the consent**.**

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Study ID: HUM00201957 / Continuing Review ID: CR00115637

Approval Date: 5/11/2026

Document Finalized: 5/12/2026 11:58 AM

UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: ENHANCING VOLUNTARY MOTION IN BROAD PATIENT POPULATIONS WITH MODULAR POWERED ORTHOSES

Company or agency sponsoring the study: National Institutes of Health

Names, degrees, and affiliations of the principal investigator and study coordinator (if applicable):

Principal Investigator: Robert D. Gregg, PhD, Department of Electrical and Computer Engineering, University of Michigan

1.1 Key Study Information

You may be eligible to take part in a research study. This form contains important information that will help you decide whether to join the study. Take the time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your family, friends, or other doctors about joining this study. If you decide to join the study, you will be asked to sign this form before you can start study-related activities. Before you do, be sure you understand what the research study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about diseases and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies do not always offer the possibility of treating your disease or condition. Research studies also have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study. For example, some studies require you to travel to scheduled visits at the study site in Ann Arbor or elsewhere. This may require you to arrange travel, change work schedules, find child care, or make other plans. In your decision to participate in this study, consider all of these matters carefully.

This research is studying the use of a new modular, powered orthoses in small numbers of people to determine its feasibility as a treatment for user-specific weakened joints (ankle, knee, and/or hip). Researchers want to understand how the orthoses work on your body and how your body will react to them. During this study you will be fitted with the modular powered orthoses by trained research staff be asked to perform various activities such as level-ground/ incline/decline walking and stair ascent/descent. No biospecimens will be collected for this research study, but we will be measuring the gases you inhale and exhale (metabolic rate testing) by asking you to wear a snug face mask designed for this purpose.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, some of these risks may include joint/muscle strain, skin irritation, and/or risk of falls. More detailed information will be provided later in this document.

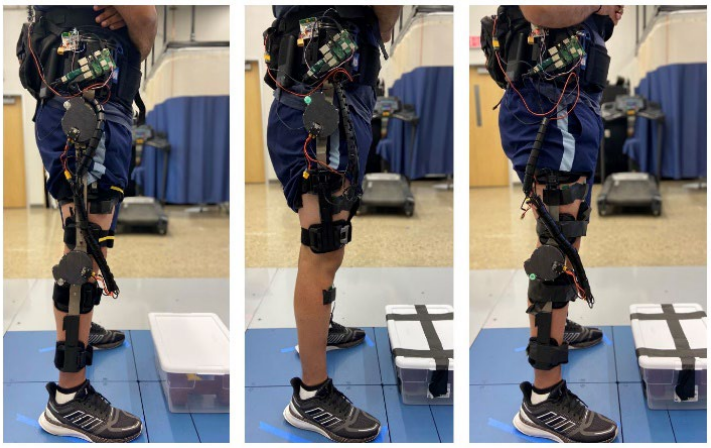


Fig 1. Modular powered orthosis in different joint configurations: (from left to right) knee and hip, hip only, knee only.

This study may not offer any benefit to you now but may benefit others in the future by enhancing the adaptability and clinical viability of future powered orthoses. More information will be provided later in this document.

We expect the amount of time you will participate in the study will be no more than five study visits up to five hours each for a total time commitment of up to 25 hours. However, you may be asked if you would be willing to return for additional study conditions with different configurations of the exoskeleton joints or controllers, where each study condition has the same maximum time commitment. Participation in any visit or study condition is completely optional. Even if you decide to join the study now, you are free to leave at any time if you change your mind.

More information about this study continues in Section 2 of this document.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

One in eight adults in the US have a mobility disorder which negatively impacts their lives. The overall goal of this project is to develop and better understand modular, lower-limb, powered orthoses that fit to user-specific weakened joints (ankle, knee, and/or hip) and control the assistance these devices provide in a way that improves voluntary motion in different types of patient populations with weakened voluntary control due to advanced age, injury, etc. Conventional orthoses tend to immobilize joints, and newer, powered orthoses constrain voluntary motion by forcing the user to follow a specific motion pattern. Because orthosis users are diverse in their needs, these populations require partial, not full, assistance of user-specific muscle groups during daily activities. However, there is a fundamental gap in knowledge about how to design and control powered orthoses to assist the user without constraining their motion. Our central hypothesis is that using small, but powerful motors that are able to be freely rotated by human joints (i.e. backdriven) will enable modular powered orthoses to partially assist various joints.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

Older adults (aged 65-90 years) who weigh less than 250lbs are eligible to take part in this study. Participants must be able to walk 6 minutes without the assistance of another person. Participants must not have uncontrolled hypertension or diabetes or significant pain due to arthritis or other joint problems that would limit their ability to walk.

Participants should not have a history of any significant cardiovascular, vestibular, visual or cognitive diseases and/or impairments that may affect their ability to walk. Participants must be able to follow directions, speak English, wear a face mask during testing, and able to give independent informed consent.

3.2 How many people are expected to take part in this study?

Thirty adults are expected to take part in this study.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

Before conducting any experiments:

1) You will first be fitted with a modular orthosis on both of your legs by trained research staff. This fitting will include aligning where the orthosis sits on your joint and ensuring you are comfortable wearing the orthosis.
2) You may then be asked to fill out the Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST 2.0) survey which asks you to rate your perceived satisfaction with the device on a five-point scale ("not satisfied" to "very satisfied") for the following characteristics of the device: 1) Dimensions (size), 2) Weight, 3) Adjustments, 4) Safety, 5) Durability, 6) Simplicity of use, 7) Comfort, and 8) Effectiveness.
3) You may be asked to fill out a modified QUEST survey which assesses your satisfaction for different tasks (sitting and standing, level walking, ramp and stairs ascent, and ramp and stairs descent).
4) You may be asked to fill out a modified WOMAC survey which assesses your perceived difficulty and pain ratings for the same tasks as the modified QUEST survey above.
5) You may be asked to rate the level of perceived intensity of physical exertion with OMNI and Borg exertion scale.

You may be asked to fill out these surveys again at subsequent visits.

For orthosis (exoskeleton) testing:

1) Trained research staff may perform evaluations, or you may be asked to complete clinical surveys so that the researchers can assess your strength and general mobility.

2) You may have electrodes placed on your skin to measure and record the electrical signals sent by your muscles.
3) You may wear an instrumented face mask to measure your exhaled and inhaled gases to assess energy expenditure for up to 15 minutes in a row at each visit. There will be at least a 10-minute break after each set of measurements with the face mask, but this can be longer if needed. The total use of the face mask across one visit will not exceed 2 hours.
4) You may have reflective markers affixed to your skin using medical grade tape in order to record your movement as you complete the experiment.
5) Before data collection starts you will have at least 30 minutes to acclimate to wearing the orthosis. During that time, you will also get to experience the different assistance levels provided and the assistance level will be adjusted to best aid you. You will then be asked to complete some or all of the following tasks both with and without the powered orthosis:
    - 10-meter walk test, repeated 3 times
    - 6-minute walk test
    - 5 times sit-to-stand or 30 seconds sit-stand, repeated up to 3 times
    - Ascending and descending a staircase, repeated up to 10 times
    - Ascending and descending a ramp (maximum 15 degrees inclination), repeated up to 10 times
    - A continuous sequence of sit-stand, ramp ascent/descent (4 meters ramp), stair ascent/descent (5 steps staircase), and walking (approximately 10 meters), repeated up to 15 times
    - Level, incline, and decline treadmill walking (up to 15 minutes per level)

If you use a walking aid such as a cane regularly then you will use it for completing the experimental tasks as well. We have limited the amount of repetitions in order to minimize fatigue and in addition to build in rests you may ask for a break at any time. You may also be asked to repeat the abovementioned tasks while wearing another commercially available brace.

With your specific consent, you may be audio/video recorded or photographed during any of the five research sessions. These photos or recordings may be used in research dissemination (for example, presentations or publications), but they will be appropriately cropped/blurred so that you are not identifiable. If you do not wish to be recorded you are still able to participate in this study.

Optional use of your information for future research

Besides the information about the main study, the following information is specific to unspecified future use of identifiable data. We would also like your permission to keep the data and medical information 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 and medical information for future research.

If you give us your permission in Section 12 of this consent form, we will use your data and medical information for future research. Even if you give us permission now to keep some of your data and medical information, you can change your mind later and ask us to destroy it. Keep in mind, however, that once we have analyzed your data, we may not be able to take the information out of our research.

We may share your data and medical information with other researchers, so that they can use it in their research. Their research may be similar to this study or may be completely different. Once we have shared your data and medical information with other researchers, we will not be able to get it back.

The main risk to this future, unspecified research is a breach of confidentiality. This risk is low and the same precautions will be taken in that your data will be store separately from any identifying information. All videos / pictures will be de-identified so that your face is not visible. Future use of your identifiable data and/or specimens will be conducted in compliance with applicable regulatory requirements. More information about confidentiality protection is provided in Section 9.1 of this consent form.

You will not find out the results of future research on your data. Allowing us to do future research on your data and medical information will not benefit you directly.

Research can lead to new discoveries, such as new tests, drugs, or devices. 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.

4.2 How much of my time will be needed to take part in this study?
For this study you may be asked to come in for up to five research visits lasting no longer than five hours each for a total time commitment of up to 25 hours. After these 5 visits, and as part of this consent, you may be asked if you would be willing to return for additional study conditions with different configurations of the exoskeleton joints or controllers, where each study condition has the same maximum time commitment. Participation in any study condition or visit is completely optional.

4.3 When will my participation in the study be over?
The entire study is expected to last 4 years, but your participation will end after your last study visit unless you agree to participate in an additional study condition.

4.4 What will happen with my information and/or biospecimens used in this study?
Your data and collected information may be shared with the National Institutes of Health.

With appropriate permissions, your data and collected information may also be shared with other researchers, here, around the world, and with companies.

Your identifiable private information or identifiable data may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

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?

This study is a non-invasive, minimal risk that involves no collection of specimens. Potential risks and prevention strategies are listed below:

1. Fatigue or exhaustion (likely).
2. Skin irritation and joint or muscle strain due to use of the orthosis (unlikely).
3. Skin irritation due to sensor tape (unlikely).
4. Mild claustrophobia or skin irritation due to the face mask (unlikely).
5. Injury from falls (rare).
6. Breach of confidentiality (rare).

The researchers will try to minimize these risks by:

1. Participants will be allowed to take breaks if they become tired at any point in the study. Additionally, there are built-in breaks to the study protocol between individual trials to minimize exhaustion.
2. Skin irritation may occur while using any orthosis. Minor muscle strain is a common problem with a new or abnormal gait and can also be caused by forces produced by a powered orthosis. Experienced research team members following current clinical practices will fit the orthosis to the participant. The participant will have ample opportunity to discuss the fit and comfort of the device and participants will be monitored for sign of discomfort. The power of the device can also be reduced in software if the participant feels it is too strong or jerky. If the participant expresses discomfort, the experiment will be paused for a break and/or equipment adjustment.
3. All sensors and markers will be affixed to participants 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.
4. Face mask for metabolic testing will be used for up to 15 minutes at a time, with at least a 10-minute rest in between tasks requiring a face mask. You may take a longer break if you would like. If the face mask becomes uncomfortable during a study task, you can remove it and resume the study task when you are ready to put the face mask back on. If you find that you do not wish to put the face mask back on, you may end the session and discuss with the researcher if you should continue participating in the study.
5. Risk of falls will be minimized by
    - requiring that all participants have the ability to walk 6 minutes without assistance.
    - Handrails will be available to grab if you lose your balance, or a researcher may follow and hold onto you with a gait belt to catch a possible fall.
    - Participants may wear a harness throughout the experiment.
    - Participants will begin with simple activities such as level-ground walking and will only be asked to perform other activities after they become proficient users of the orthosis.
    - You will be able to disable the motors through a button on the device or in your hand (e.g., if the participant feels discomfort or loses balance).

- In case of metabolic rate testing, participants will receive prior training on walking with the face mask until they are fully acclimated and feel confident.

The research team has completed extensive bench-top mechanical testing on the powered orthoses prior to use in this study to ensure durability, strength, and safety. The robotic orthoses have been designed by experts in the field with several safety features, both in software and hardware, to minimize the risk of joint or muscle soreness/injury. These devices are also designed so that participants can resist their joint motion as the force (torque) generated by the orthosis motor is about 1/3 of your joint's peak strength during walking. The orthotic joints have hardware or software stops so that the user's leg joints cannot exceed their normal range of motion at any time. Software will immediately disable the motors if onboard sensors measure any safety limit being exceeded. Despite these precautions, we are unable to guarantee that you will not experience a fall. A trained study team member will be available to assist you at all times and obtain medical help if needed.

6. Additionally, all records will be confidential, coded, and kept in a locked cabinet or on a secure network drive that only the study team has access to. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

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

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?
The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors**.**

5.3 If I take part in this study, can I also participate in other studies?
Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?
You may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?
Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?

There are no other options if you decide not to take part in this study. Your decision to participate is voluntary.

7. ENDING THE STUDY

7.1 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 choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 "Contact Information".

7.2 Could there be any harm to me if I decide to leave the study before it is finished?

None.

7.3 Could the researchers take me out of the study even if I want to continue to participate?

Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

There are no costs or billing for this study, other than the cost to travel to the study site.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?

You will be paid $40/hour in order to compensate you for your time and travel to the research site. This payment will be mailed to you via a check upon your completion of the study. If you withdraw or are removed from the study before completion, you will receive $40/hour based on the number of hours you participate. This will also be mailed in the form of a check.

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

The investigators and institution may have proprietary interests in the technology involved in this study, including patents and potential licensing agreements. This study is supported by the National Institutes of Health, which will not benefit financially from the study results.

Research can lead to new discoveries, such as new tests, drugs, or devices. 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.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND YOUR HEALTH INFORMATION

The information below describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

9.1 How will the researchers protect my information?
All data collected from participants will be considered privileged and held in confidence: participants will be assigned confidential codes and no identifying personal data will be stored with study data. Study data will be stored in a secure UM ARC Turbo Research Storage drive (for sensitive data), UM Dropbox, or in the PI's locked filing cabinets as applicable.

Each participant will be identified with a participant code, and filenames will be labeled with the participant code instead of participant name. The participant name - participant code link will be stored in a locked file cabinet. In the case that the results of this data are published, the participants will be referenced through the participant code and the identity of the research participants will not be indicated. If a participant gives specific permission on the consent, he/she may be photographed and videotaped during the experiment for possible use in scientific presentations, publications, or public dissemination. All photographs and videos will be stored with study data in a secure UM server or UM Dropbox.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institutes of Health which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

A description of this clinical trial will be available on http://www.clinicaltrials.gov/, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

9.2 What health information about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- If you receive any payments for taking part in this study, the University of Michigan finance department will need your name and address for tax reporting purposes. In a calendar year if: 1) your payments total greater than $400 for this study or 2) if you receive payments of greater than $400 for being in more than one study, the University of Michigan finance department will also require your Social Security Number for tax reporting purposes. If you do not wish to provide your Social Security Number, you may continue to participate in research studies, but you will not be able to receive payment for the remainder of the calendar year.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.

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

9.3 What happens to information about me after the study is over or if I cancel my permission to use my health information?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission to use my health information expire?

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below).

10. CONTACT INFORMATION

10.1 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 or treatments
- Talk about study-related costs to you or your health plan
- 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: Robert Gregg, PhD
2505 Hayward St., Room 2260
Ann Arbor, MI 48109
(734) 763-1156
rdgregg@umich.edu

You may also express a question or concern about a study by contacting the Institutional Review Board listed below:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214

Ann Arbor, MI 48109-2800
Telephone: 734-763-4768 (For International Studies, include the appropriate calling codes.)
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.
When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?
Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)*

12. SIGNATURES

Sig-A

Consent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Print Legal Name: _____

Signature: _____

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

Sig-B

Consent to video/audio recording/photography solely for purposes of this research
This study involves video and/or audio recording and/or photography. If you do not agree to be recorded, you CAN STILL take part in the study.

_____ Yes, I agree to be video/audio recorded/photographed.

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

Print Legal Name: _____

Signature: _____

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

Sig-D

Consent to Collect for Unspecified Future Research
This project involves the option to allow the study team to keep your identifiable data for use in future research. I understand that it is my choice whether or not to allow future use of my data. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

_____ Yes, I agree to let the study team keep my data for future research.

_____ No, I do not agree to let the study team keep my data for future research.

Print Legal Name: _____

Signature: _____

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

Sig-G

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Printed Legal Name: _____

Title: _____

Signature: _____

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