Usability of the MeTime MS Acupressure mobile application in adults with MS

2/24/2025

NCT07123272

UNIVERSITY OF MICHIGAN

CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Usability of the MeTime MS Acupressure mobile application in adults with MS

Company or agency sponsoring the study: Health and Human Services, Department of National Institutes of Health

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

Principal Investigator: Anna Kratz, PhD, Department of Physical Medicine and Rehabilitation, University of Michigan

Study Coordinator: Kristi Pickup, LMSW, Department of Physical Medicine and Rehabilitation, 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 childcare, or make other plans. In your decision to participate in this study, consider all these matters carefully.

This research is studying the usability of a newly adapted mobile app for self-administered acupressure for pain and fatigue in adults with MS, “MeTime MS”. The MeTime MS app has been tailored to be more relevant to the MS population. Before conducting a trial of self-acupressure for pain and fatigue in adults with MS, we aim to first conduct a usability study of the adapted MeTime MS app in a small sample of adults with MS. You will be asked to use one of two versions of the app – one demonstrates a stimulating acupressure protocol, and one demonstrates a relaxing acupressure protocol – for 6 weeks. After the 6-week period, the study team will ask you questions about your experience with the app (not with the acupressure itself) either individually or in a group.

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 mild bruising at points of pressure if too much pressure is applied. More detailed information will be provided later in this document.

This study may offer some benefit to you now, or others in the future, by ensuring that the MeTime MS app is usable and relevant to the MS population. This study may not offer any benefit to you now but may benefit others in the future by allowing us to use the MeTime MS app to test the effectiveness of self-administered acupressure for pain and fatigue in MS in the future. More information will be provided later in this document.

We expect the amount of time you will participate in the study will be up to 10 weeks.

You can decide not to be in this study. 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:

This study is designed to assess the usability of a newly adapted mobile app called MeTime MS. Dr. Kratz adapted an existing mobile application (MeTime), which was originally developed in association with patient focus groups consisting of cancer survivors and the University of Michigan 3D Media Laboratory. The adapted app, MeTime MS, has been tailored to be more relevant to the MS population, including an updated MS-specific introduction video. Before conducting a trial of self-acupressure for pain and fatigue in adults with MS, we aim to first conduct a usability study of the adapted MeTime MS app in a small sample of adults with MS.

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?

You may be eligible to participate in this study if you have been diagnosed with Multiple Sclerosis and experience both chronic pain and chronic fatigue.

You must have the following to take part in the study:

1. Have an MS diagnosis (all MS subtypes included; diagnosis confirmed by medical record review);
2. Are 18 years of age or older;
3. Experience chronic pain, that is moderate to severe and has lasted at least 3 months;
4. Experience chronic and problematic fatigue that, in your opinion, has interfered with your daily activities for at least 3 months;
5. Have home access to internet via Wi-Fi or cellular data;
6. Have an active email account.

You cannot be part of the study if you have any of the following:

1. Are not fluent in English;
2. Are pregnant, breastfeeding, or anticipate becoming pregnant in the next 6 months;
3. Inability to use the study equipment (e.g., smartphone/tablet or smartphone mobile application);
4. Anything at the discretion of the PI or study team that would preclude participation in the study.

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

We expect that 10 adults with MS will participate in this study.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

Once we have received your consent, you will be asked to complete a brief 5–10-minute online survey with questions about demographics, medications for pain and/or fatigue, fatigue level, pain level, and level of functioning. You will also be asked to attend a 30–60-minute virtual baseline visit over Zoom. At this visit, a study coordinator will give you access to one of two versions of the app (stimulating or relaxing), explain how to use the MeTime MS app, show you the acupressure points, and demonstrate how to self-administer acupressure.

We will send you an acupressure tool (a pencil with a large eraser), which will help you apply the right amount of pressure on the appropriate points on your body. You may also use your thumb or finger. You will be given the option to borrow a study phone or use your personal smartphone or tablet. If you choose to borrow a study phone, the app will be pre-downloaded and sent with the acupressure tool. If you choose to use your personal device, you will be shown how to download the app. You will then be asked to use the app on your own for 6-weeks. The app will ask you to perform daily acupressure, which is about 30-minutes per day. A study coordinator will call you each week to make sure everything is going well.

After the 6 weeks using the app, you will be asked to complete another brief online survey (around 2 minutes) asking about your experience with using the MeTime MS app. You will also be asked to participate in a 30-minute one-on-one interview or a 30–60-minute focus group where you will be asked for your feedback and impressions of the app. You will be asked about the app's ease of use, relevance to MS, etc. In this study, we are *not* assessing effects of the acupressure on symptoms or functioning. You will only be asked about how the app was to use and if there is anything that you would change about the app to make it easier to use.

For some research studies, it is important that you do not learn the results of certain tests. Whether you intend it or not, sometimes learning this information may make you change your actions and behaviors in ways that could impact the outcome of the study.

As a subject participating in this research study, you have certain responsibilities that may apply to this study, such as ensuring that you arrive at all your scheduled virtual appointments, use the MeTime app as directed, and report any negative experiences you may have during the study.

Besides the information about the study, the following information is specific to unspecified future use of identifiable data and/or biospecimens. We would also like your permission to keep some of your 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 study even if you decide not to let us keep your medical information for future research.

If you give us your permission, we will use your medical information for future research. Even if you give us permission now to keep some of your medical information, you can change your mind later and ask us to destroy it.

We may share your 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 medical information with other researchers, we will not be able to get it back.

Future use of your identifiable data and/or specimens will be conducted in compliance with applicable regulatory requirements.

Allowing us to do future research on your medical information will not benefit you directly.

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

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

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?

Over the course of 10 weeks, we estimate the following time will be needed for the study:

- **Baseline visit:** The baseline visit will take place virtually and is expected to last about **30 minutes**.
- **Online assessments:** You will complete 2 online assessments: at the beginning of the study (**5-10 minutes**), and the end of the study (around **2 minutes**).
- **6-week app use period:** Per app instruction, you will complete acupressure once per day for **6 weeks** after the beginning of the study. The acupressure takes about **30 minutes each day** to complete. A study coordinator will call you once per week for the 6-weeks to ensure everything is going well. This call may be **1-5 minutes** per week.

4.3 When will my participation in the study be over?

Your participation in the study will be over after you have completed the one-on-one interview or focus group.

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 known or expected risks are:

- Potential non-serious mild bruising at points of pressure if too much pressure is applied. This bruising should not continue or get worse.
- Potentially feeling uncomfortable, frustrated, bored, or inconvenienced when completing the study surveys.

The researchers will try to minimize these risks by:

- Having an acupressure educator train you in how to apply the correct amount of pressure with your thumb, finger, or other tool; and specific attention will be taken to avoid exerting excessive pressure. Additionally, a member of research team will call you at certain times during the study to evaluate your health and safety. During these conversations we will ask you about any bruising.
- Allowing you to complete the online surveys from home and skip any question that you are not comfortable answering.

Additionally, there may be a risk involving loss of confidentiality or privacy. For example, if individuals outside this study were to discover that you were a participant in this research, or if any collected identifiable genetic or health information were disclosed to unauthorized persons, there is a risk of discrimination by employers or insurance providers. The researchers have adopted privacy and confidentiality procedures to help prevent such disclosures. 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.

Keep in mind, as well, that the committee (IRBMED) that reviews this study does not review risks associated with procedures that are conducted as part of your regular medical care and are not part of the research, including those marked "[Not research]" in section 4.1, above. Risks associated with your regular medical treatment should be discussed with your regular doctor.

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 or any other provider or hospital you visit**.**

A member of research team will call you each week during the study to evaluate your health and safety as related to your use of the MeTime MS app. If mild bruising is reported, the study team member will help you to adjust the pressure you are using and provide further guidance.

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, it is possible that the acupressure could improve symptoms of fatigue or pain. Others may benefit from the knowledge gained from this study about the use of the MeTime MS app.

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?

You can decide not to be in this study. Treatment options for pain and fatigue should be discussed with the physician who is treating your MS.

Though this study is not testing any effects of acupressure on pain or fatigue, you may wish to pursue acupuncture or acupressure by a licensed practitioner to treat your fatigue or pain if you decide not to participate in this research study.

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?

Tell us if you are thinking about stopping or decide to stop. It is important to tell us if you are thinking about stopping so any risks can be evaluated by the researchers. We will also tell you how to stop safely and discuss what follow-up care and testing could be most helpful for you. If you decide to leave the study before it is finished, please tell one of the researchers listed in Section 10 “Contact Information” (below).

You are free to end your participation partially or completely in the study. An example of partially ending your participation would be to discontinue using the app, while still allowing continuation of study follow-up procedures.

Please note that any information collected before you withdraw will be kept and used to complete the research.

Please note that even if you withdraw consent for further follow-up or contacts, if the study PI becomes aware of additional safety information this will be reported to the sponsor to comply with legal or regulatory requirements.

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 researchers believe 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.

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

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

You will be compensated a total of $100 for participating in the study ($25 for the baseline survey and $75 for the interview/focus group).

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

No one stands to profit or financially benefit 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 PARTICIPANT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED 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?

Your participation will occur at Michigan Medicine. Your data will be kept confidential, to the extent permitted by applicable laws, in the following manner:

- Your name will not be used in any reports about the study
- You will be identified only by a study code
- Your identifying information will be kept secure

Despite these protections, some study data may contain information that could be used (perhaps in combination with other information) to identify you (e.g., initials, date of birth).

All data and information collected in the study will be used for research purposes only. Research data will be stored electronically in a password protected database accessible to only study team members. Any paper study materials will be stored in a locked cabinet. Your research will not be made a part of your regular medical record. However, if the researcher orders any tests, the order and results may become part of your regular medical record.

Research records will be kept in a separate research file that does not include names, registration numbers, or other information that is likely to allow someone other than the researchers to link the information to you. All electronic records will be kept in a password-protected database accessible only to study team members.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that we cannot release or use information, documents, or samples that may identify you in any action or suit except as described below. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other legal proceedings. An example of a situation in which the Certificate would apply would be a court subpoena for research records.

There are some important things that you need to know:

- The Certificate does not stop reporting or information-sharing that you agreed to in this consent document. For example, [Cite examples as apply to your research] we may share information with appropriate authorities if we think you may harm yourself or others. We may also share your information with other researchers.
- The Certificate does not stop reporting that federal, state, or local laws require. Some examples are laws that require reporting of child or elder abuse and of some communicable diseases.
- The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs.
- The Certificate does not stop disclosures required by the federal Food and Drug Administration (FDA).
- We may also release information about you to others when you say it is okay. For example, you may give us permission to release information to insurers, medical providers, or anyone else.
- The Certificate of Confidentiality does not stop you from personally releasing information about your involvement in this research if you wish.

More information about Certificates of Confidentiality and the protections they provide is available at https://www.era.nih.gov/erahelp/CoC_Ext/Content/A-Introduction/Introduction.htm

9.2 What protected health information (PHI) 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 for you to take part in the study.

Medical information and billing records are protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). This type of information is called protected health information (PHI). PHI about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
- All records relating to your condition, the treatment you have received, and your response to the treatment
- Demographic information
- Personal identifiers
- Other information

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 and for quality improvement purposes.
- 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
- Insurance companies or other organizations may need the information to pay your medical bills or other costs of your participation in 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 PHI?

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

If 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 PHI expire?

Your permission does not expire unless you cancel it. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below). If you withdraw your permission, you may no longer be eligible to participate in this study.

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:	**Anna Kratz, PhD**
Mailing Address:	2800 Plymouth Rd, NCRC B016-G017W, Ann Arbor, MI 48109
Telephone:	734-647-5982
Study Coordinator:	**Kristi Pickup, MSW**
Mailing Address:	2800 Plymouth Rd, NCRC B016-G151S, Ann Arbor MI 48109
Telephone:	(734)-764-4072

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?

You will receive a copy of the signed and dated informed consent document.

Your signature in the next section means that you have received a copy of the following document(s):

- 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.)*
- Other (specify):_____

12. STORAGE, USE, AND SHARING OF SPECIMENS AND INFORMATION COLLECTED OR GENERATED IN THE STUDY DESCRIBED ABOVE

12.1 What is meant by the storage, future research use, and sharing of study participants' medical information and leftover samples (sometimes referred to as biospecimens) taken from me?

Individual researchers, the University of Michigan, and companies that design and sponsor studies often want to keep subjects' medical information and leftover samples such as blood, tissue, saliva, and cells to use in future research. These future research uses take different basic forms, which are described below. The medical information and leftover samples may also be shared with other researchers so that they can use it in their studies.

The purpose of storing, using, and sharing participants' medical information and leftover samples is to promote more research that might lead to useful medical discoveries.

In some cases, researchers need your consent to store, use, and share your medical information and leftover samples; in other cases, they can store, use and/or share it without your consent. Whether or not researchers need your consent depends on if the stored information and samples would still be identifiable as yours or whether the researchers would first remove all information connecting them back to you.

12.2 Types of storage, future research use, and sharing in this study

For purposes of this research study, your collected private information and any biospecimens will be shared with the study sponsor, the National Institutes of Health, its collaborators, and associated research partners.

With appropriate institutional and regulatory permissions, your collected private information and identifiable biospecimens could be used for future research with other researchers and companies, including those in other countries, with or without your consent.

In addition, after identifiers are removed from your private information and any biospecimens, the information and biospecimens could be used for future research studies by U-M and shared with other researchers or companies, including those in other countries, without your additional informed consent.

In each of the situations described below, you may later change your mind and withdraw your consent to the storage, use, and sharing of your information even if you give consent now, provided that the information can still be identified as yours, has not already been used or shared, or has not been added to your medical record. Keep in mind, however, that any information that has already been used or shared with other researchers, as well as any information that has been added to your medical record, cannot be recovered, or deleted.

The National Institutes of Health (NIH)'s Data Management and Sharing (DMS) policy, which took effect in January 2023, requires researchers receiving NIH funding to develop plans for making research data available to other researchers, in accordance with criteria and definitions outlined in the policy, which can be viewed here.

NIH's policy does not forbid what it refers to as the "open sharing" of data, meaning utilization of sharing mechanisms that are publicly available without securing special authorization from the data's holders. Open sharing is permitted provided that it occur "in ways that are consistent with consent practices [this includes compliance with all federal and institutional consent requirements], established norms, and applicable law" and "as long as participants are appropriately informed and prospectively agree to them."

This study receives funding from the National Institutes of Health (NIH). NIH requires us to develop a plan regarding how we may share some information about you with other researchers so that they can use it in their studies. Their research may be similar to this study or may be completely different. Once we have shared information about you with other researchers, we will not be able to get it back.

Although we will do our best to protect your information, both during storage and when sharing it with others, it's possible that unauthorized people might gain access to your information.

We will remove all details from your information that identify you individually and assign it a random code before sharing it with other researchers. Once we have removed and destroyed those identifying details, it will be impossible for others to know the information came from you.

Researchers who wish to access your information must obtain permission to access your information.

You will not find out the results or directly benefit from future research utilizing your information. Sharing your information may contribute to research that helps others in the future.

You do not have to agree to storage and sharing of your information if you do not wish to. You may take part in this study even if you do not want us to share your information with other researchers. You will indicate your choice regarding storage and sharing of your information in a signature box at near the end of this document.

13. 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 [NAME OF STUDY TEAM MEMBER OBTAINING CONSENT] _____. 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-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): _____