

UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

INFORMATION ABOUT THIS FORM

You may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study.

Please take time to review this information carefully. After you have finished, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or other doctors) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. *Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.*

1. GENERAL INFORMATION ABOUT THIS STUDY AND THE RESEARCHERS

1.1 Study title:

The impact of metabolic syndrome on the incidence of neuropathy in obese subjects.

1.2 Company or agency sponsoring the study:

A. Alfred Taubman CA&UP Administration
American Diabetes Association
Impeto Medical
Neurology Department
Department of Health and Human Services, National Institutes of Health

1.3 Names, degrees, and affiliations of the researchers conducting the study:

Dr. Brian Callaghan, M.D.	Principal Investigator
Dr. Charles Burant, M.D., Ph.D.	Co- Investigator
Dr. Eva Feldman, M.D, Ph.D.	Co- Investigator
Dr. Rodica Pop-Busui, M.D.	Co- Investigator
Dr. Amy Rothberg, M.D.	Co- Investigator
Dr. Ann Little, M.D.	Co-Investigator
Dr. James Teener, M.D.	Co-Investigator
Dr. Henry Paulson, MD, PhD	Co-Investigator
Dr. Bruno Giordani, PhD	Co-Investigator
Dr. James Richardson	Consultant
Bin Nan, BS, MS, Ph.D.	Consultant
Emily Villegas-Umana, RN, BSN	Study Coordinator/Project Manager
Ericka Chant, MPH	Study Coordinator/Project Manager
Jayna Duell, RN, BSN	Study Coordinator/Project Manager
Carey Backus, B.A.	Staff
Crystal Pacut, B.S.	Staff

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

The purpose of our study is to show that obesity and its associated medical problems affect how likely an individual is to develop peripheral neuropathy. Neuropathy is nerve damage which often causes numbness, pain, and tingling, usually beginning in the feet. The problems associated with obesity that we are interested in studying for this study include excess fat (especially around the mid-section), problems with cholesterol and

triglycerides (fat in the blood), high blood pressure, diabetes and other problems with your body's processing of sugar and insulin. These factors together are referred to as the metabolic syndrome.

Thin participants of the same age and gender without any factors of the metabolic syndrome will also be included in this study to see if they are less likely to develop neuropathy than individuals with obesity and other factors of the metabolic syndrome.

3. INFORMATION ABOUT STUDY PARTICIPANTS (SUBJECTS)

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 included in the study if:

- You are at least 18 years old and are able and willing to provide written informed consent for the study.
- You are enrolled in the Investigational Weight Management Clinic (IWMC). This is the weight management program through the Department of Endocrinology which is helping you to lose weight.
- You are enrolled in the IWMC's associated research study (HUM00030088) called "Identification of phenotypic factors that predict success for weight loss and long-term weight maintenance" and agree to be contacted regarding other studies related to obesity.

You may not be included in the study if:

- You are taking any blood-thinning medications (anti-coagulants), other than aspirin.
- You are not participating in the IWMC and/or its associated research study (HUM00030088), either due to lack of interest or because you were not eligible to participate.

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

Up to 400 obese participants and 200 thin participants are expected, for a total of up to 600 participants.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

The following will occur at the beginning and end (2 years after study initiation) time points of the study. We will be repeating all of the testing after two years to see how your weight loss, increased exercise, and/or the passage of time will affect each of these measures.

- We will test for any changes in the nerves that surround your heart by recording your heart rate, blood pressure, and breathing at rest compared to during a regulated breathing exercise, when you stand up, and when you blow into a mouthpiece. This takes about 60 minutes to complete and is called Heart Rate Variability testing. You will lie flat and quietly for 20 minutes before the recording begins and must follow special preparation instructions for this test provided by the study coordinator.
- We will apply a small electric current to the skin at the ankle, knee, wrist and elbow in a test called Nerve Conduction Studies. This feels similar to a static shock and is used to measure the health of the nerve being tested. This will take 30-45 minutes to complete.
- We will measure how much you sweat which will tell us about how much your body's system is able to control your sweating. This body system is called your autonomic nervous system. We will use two tests to measure your sweat function, the QSART and the SUDOSCAN tests.
 - During the QSART test, plastic straps will be used to secure a small capsule to the forearm, knee, ankle and foot. A liquid solution called acetylcholine will be put into the capsules so that it touches that skin

and causes it so sweat. Your sweat output beneath the capsules is then measured. This takes about 20 minutes to complete and often causes a “pins and needles” sensation.

- You will be asked to complete a SUDOSCAN test, unless you have an embedded pacemaker or defibrillator. The SUDOSCAN device will be used to measure your how well your skin produces sweat. You will be asked to place your bare hands and feet on stainless-steel electrode plates, and a Direct Current of less than 4 volts total will stimulate your sweat glands. This is a fast, 3-minute, non-invasive, pain-free test that will scan the soles of your feet and the palms of your hands. You will be instructed to take off your shoes and socks and roll up your pants, shirt sleeves, remove any large obtrusive jewelry and wash off lotion.
- You will be examined by a neurologist who specializes in nerve and muscle problems, including neuropathy (neuromuscular specialist). He/she will ask you some questions about yourself, any medical problems that you may have, any symptoms that are consistent with neuropathy, and do a brief physical examine. The examine will include things such as checking your reflexes; checking how well you can feel vibration, cold, and pinprick sensations; watching you walk; and looking at your feet for any signs of neuropathy. He/she will complete the Michigan Neuropathy Screening Instrument which includes 15 questions about nerve symptoms and a neurologic examination, as well as a standardized Neurological Exam form geared towards assessing neuropathy.
- You will be asked to complete some questionnaires as part of participation in the study. This will be completed either at home before your study visit or at the time of the visit, as instructed by the study coordinator:
 - A neuropathy-specific quality of life questionnaire named NeuroQoL. This questionnaire will assess if and how symptoms of neuropathy have affected your quality of life. This will take about 15 minutes to complete.
 - The McGill Pain Questionnaire. This questionnaire assesses the level of pain that you experience in your feet. This should take less than 5 minutes to complete
 - Two surveys related to symptoms that appear if you may have problems with the nerves which control the autonomic system. The autonomic system is the body system which controls muscle function which you do not have direct control over, such as your heart and digestion. The surveys are called the Survey of Autonomic Symptoms and Autonomic Symptoms Profile and may take you up to 15 minutes to complete.
 - A brief eight question survey to assess risk for obstructive sleep apnea, called the STOP-BANG questionnaire.
- You will be asked to stand on one foot for a period of time to evaluate any problems with balance that you may because balance can be affected in individuals with neuropathy. You will also be asked lie on your side and raise your hips from the ground and maintain this position. This is called a plank test will be informative regarding how abdominal or hip strength may affect balance.
- We will measure how well you can feel cold and vibration sensations in your feet because these sensations are often reduced in individuals with neuropathy.
 - One of these tests is called Quantitative Sensory Testing (QST). For this test, a device is placed on or attached to your foot which provides a temperature change or vibration sensation. You will indicate when you feel the vibration or cold sensation through a hand-held responder. This takes approximately 20 minutes.
 - Another simple tool called a neurothesiometer will be used to assess vibration sensitivity at your toe. For this test, a vibration stimulus will be placed on your toe. The intensity of the vibration will be

increased until you can feel it and then decreased until you can no longer feel it. This takes approximately 10 minutes.

- We will use a computer-based program to assess your thinking, reasoning, and remembering skills. We are looking to see if the nerves in the brain are affected in a similar way to the nerves that go to the legs and arms. The computer program is called CogState and is a 15-20 minute computerized screening comprised of playing card tasks.
 - *In addition to the measurements when you join the study and two years later, the CogState will also be completed approximately 1 month and one year after you begin your diet. A member of the study team will meet you before or after your 3 month and 1 year visit (+/- 1 visit or 4 weeks) with the IWMC at Domino's Farms to repeat the CogState computerized screening OR you will be contacted to complete this testing on your own computer at home.*
- We will look for vision problems by having you look into an instrument which will display multiple visual targets. You will indicate that you have seen the target by pressing a response button. This is called Frequency Doubling Technology (FDT) Perimetry. You will need to wear any corrective lenses or contacts that you use to see in the distance for this study. This exam is called the 24-2 FDT.
- You will have two pieces of the top layer of skin removed in a procedure called a skin biopsy. One biopsy will be taken from near your left ankle and the other will be taken from your upper left thigh. The skin samples, or biopsies, will be 3-millimeters (approximately 1/10th of an inch or this ○ size) across. The skin will be numbed with a numbing medicine called lidocaine with epinephrine before the biopsies are taken by a trained nurse who will give you instructions on how to care for the biopsies after you go home. We will be measuring how many nerves fibers you have in the skin because some individuals with neuropathy have less nerve fibers in their skin. This should take 30-45 minutes to complete.

In addition, the following will be done as part of this study OR collected from the IWMC at the beginning of the study, after 3-9 months, and at the end of the study (after 2 years). If any of the below were done by a doctor other than your IWMC doctors, we will ask your permission to collect this information from that doctor(s) and have you sign a release of records form to collect this data from your other doctor(s):

- A blood draw which will be used to order lipid panel to check your HDL and LDL cholesterol, as well as triglycerides levels (fat in the blood). Approximately one milliliter of blood will be drawn for this.
- If you are not known to be diabetic, an oral glucose tolerance test will be performed at the beginning of the study, 3-9 months, and end (24 months) of the study. For this test, you will be asked to drink a sugary liquid, also known as glucola. One milliliter of blood will be taken before you do this and at set time points after you drink the liquid. The amount of sugar, or glucose, in your blood will be measured at these time points to check for diabetes, pre-diabetes, impaired fasting glucose, or impaired glucose tolerance.

Data collected for clinical purposes as part of the IWMC and its associated research study HUM00030088 will be reviewed as part of this study and included in your study records.

4.2 How much of my time will be needed to take part in this study?

- One 5-hour visit at the beginning of the study and one 5-hour visit 2 years later at the end of the study will be required for participation.
- In addition, there may be a visit 3-9 months after the first visit to repeat the glucose tolerance test and/or lipid panel if it is not being done as part of routine care or as part of participation in the IWMC. This visit will take between 15 minutes and 2.5 hours, depending on the need for a repeat glucose tolerance test or lipid panel.
- Two 15-20 minutes visits at your 12 and 52 week visit (+/- 1 visit or 4 weeks) with the IWMC to repeat the CogState computerized screening.

4.3 When will my participation in the study be over?

Your participation in the study will be over after completion of the study visit 2 years after initiation of the study, which includes all measures mentioned in section 4.1.

5. INFORMATION ABOUT 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:

- Heart rate variability testing: You may find the testing procedures to be unusual and/or confusing and repeated blood pressure measurements may be uncomfortable for you. The research member administering the tests will give you instructions which will help prevent confusion and check to make sure that the blood pressure measurements are not too uncomfortable for you.
- The nerve conduction studies described above have the risk of discomfort due to the static current of electricity applied to the skin. These feel like a static shock and are discomforting to some people but do not have any other risks involved. The researchers will try to minimize these risks by having the procedure performed by licensed and trained members of the research team and taking the time to explain the procedure to you and making you as comfortable as possible during the testing.
- Sweat testing:
 - QSART: The QSART testing has the risk of discomfort due to the placement of the strap and electrode used in the testing. The strap needs to be tightly secured and this is sometimes uncomfortable. The solution used during the testing may cause a tingling or slight burning sensation to the skin such as an insect bite would. You may develop a rash in the areas where your skin is exposed to the solution. The researchers will try to minimize these risks by having trained members of the research team perform the test and by taking the time to explain the procedure to you and make you as comfortable as possible during the testing.
 - SUDOSCAN: There are no known side effects or risk from the SUDOSCAN.
- Questionnaires and doctor's exam: Any questions asked about a person's health and well-being or doctor's exam may cause you some discomfort in answering but is no more so than any standard health questionnaire or doctor's visit. The researchers have tried to minimize this risk by using standard questionnaires that have been used in the health practice for many years.
- Measurements of cold and vibration sensitivity:
 - QST: some people may find the strapping of the device, the vibration sensation, or the cold sensation to be uncomfortable. The research member conducting the test will read you instructions prior to the testing procedure and you will be given the opportunity to ask any questions before testing begins.
 - Neurothesiometer testing: there are no known risks of using the neurothesiometer. The research member conducting the test will read you instructions prior to the testing procedure and you will be given the opportunity to ask any questions before testing begins.
- Balance and strength measures: Some people may find performing the balance and strength measures to be difficult, strenuous, or uncomfortable. If you have any health conditions which prevent you from being able to perform these measures, please notify the study team so that they can be modified to prevent discomfort or pain.
- Cognitive testing: There are no known risks of performing this cognitive screening, other than any discomfort associated with using a computer or stress that you may experience during this evaluation.

- Visual testing (24-2 FDT): there are no known risks of this testing. The research member conducting the test will read you instructions prior to the testing procedure and you will be given the opportunity to ask any questions before testing begins.
- Skin biopsies: The skin biopsies have the risk of discomfort or pain from the needle stick to numb the area to be biopsied. During the biopsies, you may experience some bleeding and bruising, there is a small risk of infection. There is a risk of scarring at the site of the biopsy. There is also the possibility of a reaction to the numbing medicine (lidocaine with epinephrine) used to perform the biopsy. Please notify study personnel if you have a history of allergic reactions to local anesthetics. The researchers will try to minimize these risks by having trained members of the research team perform this procedure and using sterile technique and equipment in the performance of this procedure. A bandage will be applied to the biopsy sites after the procedure and you will be given instructions on care of the wound. The instructions also have contact information for the study team if you have any questions or concerns after the procedure.
- Blood draw for the lipid panel and glucose tolerance test: blood drawing is mildly painful from the insertion of the needle and can cause bruising and very rarely fainting, blood clots, or an infection at the needle stick site.
- Glucose tolerance test: Drinking the sugary liquid may be uncomfortable or unpleasant for some individuals and may cause your blood sugar to rise temporarily. In some individuals, sugar levels will then fall below a comfortable range by the end of the test. Blood drawing will be done by experienced personnel to minimize discomfort. Blood sugar levels will be checked before you drink the sugary liquid to make sure your blood sugar levels are not too high to safely drink the sugary liquid and before you leave to make sure that they are in a safe range. A snack will also be provided at the end of the glucose tolerance test to prevent any discomfort related to low blood sugar.

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 will also be given an instruction sheet after the biopsies are completed that has contact information for the research team. You should also tell your regular doctors of any complications or side effects that you feel are as a result of participation in this study.

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. However, there is no conflict or problems in participating in this study in addition to the IWMC's research study HUM00030088 and no prior approval is necessary to participate in these two studies simultaneously.

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. The study is designed to collect information to determine if obesity and the metabolic syndrome have any relation to peripheral neuropathy and its treatment. You may, however, request records for yourself or your doctor(s) of your lipid panel and/or glucose tolerance test and a summary of your nerve conduction studies and/or neurologic exam.

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. OTHER OPTIONS

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

There is no penalty to you if you choose not to participate in this study or to complete all study procedures. You still will be treated at the University of Michigan with your regularly covered care.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?

If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 “Contact Information” (below). 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.

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

There is no harm to you in leaving the study before it is finished. The researchers may contact you to ask you if you would be willing to complete any unfinished procedures prior to leaving the study.

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?

The study will pay for research-related items or services that are provided only because you are in the study. If you are not sure what these are, see Section 4.1 above or ask the researchers for a list. If you get a bill you think is wrong, call the researchers’ number listed in section 10.1.

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care
- Monitoring for side effects or other problems
- Treatment of complications

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Section 10 below or call your health plan’s **medical reviewer**.

There is no compensation for research-related injury.

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?

Yes. You will be paid \$100 after completing **all** of the procedures at the beginning of the study and \$100 after completing all of the procedures at the end of the study at the end of year 2. This is to help compensate for your time and travel expenses but will not necessarily cover all of these costs. The cost of parking will also be compensated at each visit.

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

No one will profit financially from the study results including the researchers and the University of Michigan. The knowledge to the scientific community is the only benefit to this study.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how your privacy and the confidentiality of your research records will be protected in this study.

9.1 How will the researchers protect my privacy?

Your privacy will be covered and protected under the University of Michigan's policies and procedures for the protection of health and personal information (HIPAA) policy. The researchers will remove any identifiers from your records and will assign your information a research code. This code will be the only link to your information. The key to this code and your personal identifiers will be only available to members of the research team and be kept in a locked and/or password protected file and will be destroyed at the end of the analysis of the research when it is no longer needed.

9.2 What 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. Information 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 weight management and/or neuropathy, the treatment you have received, and your response to the treatment
- Alcohol/substance abuse treatment records
- Your AIDS/HIV status
- Billing 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.
- The researchers may need the information to check your test results or look for side effects.
- University, Food and Drug Administration (FDA), and/or other government officials 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
- Insurance companies or other organizations may need the information in order 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.
- Information about your study participation may be included in your regular UMHS medical record.
- If you receive any payments 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.
- 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?

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.med.umich.edu/hipaa/npp.htm>. 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 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: Dr. Brian Callaghan
Mailing Address: 109 Zina Pitcher Place
4021 AAT BSRB
Ann Arbor, MI 48109-2200
Telephone: 734-764-7205
734-936-6267 pager 16266

Study Coordinators: Emily Villegas-Umana
Mailing Address: 109 Zina Pitcher Place
4019 AAT BSRB
Ann Arbor, MI 48109-2200
Telephone: 734-615-9891
734-936-6267 pager 37801
Email: lignonemi@med.umich.edu

Mailing Address: Ericka Chant, MPH
109 Zina Pitcher Place
4019 AAT BSRB
Ann Arbor, MI 48109-2200
Telephone: 734-764-6380
734-936-6267 pager 39922
Email: echant@med.umich.edu

You may also express a concern about a study by contacting the Institutional Review Board listed below, or by calling the University of Michigan Compliance Help Line at 1-888-296-2481.

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
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy, contact the University of Michigan Health System Privacy Officer at 1-888-296-2481.

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

Research Subject:

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 for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Signature of Subject: _____ Date: _____

Name (Print legal name): _____

Patient ID: _____ Date of Birth: _____

Principal Investigator (or Designee):

I have given this research subject (or his/her legally authorized representative, if applicable) information about this study that I believe is accurate and complete. The subject has indicated that he or she understands the nature of the study and the risks and benefits of participating.

Name: _____ Title: _____

Signature: _____ Date of Signature: _____