**********DO NOT DELETE OR ALTER THIS PAGE**********

CAUTION: IF YOU HAVE PRINTED THIS CONSENT FOR USE WITH PARTICIPANTS, IT IS NOT THE IRBMED APPROVED VERSION. Access the approved/watermarked consent from the Documents Tab in the main study workspace. The approved/watermarked document *will not* contain this cover page and *will* have the approval watermark present in the header.

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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**.**

---------- **IRB OFFICE USE ONLY** ----------

Study ID: HUM00078942 / Amendment ID: Ame00090119

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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

Study title:
Pain Control Using Neuromodulation in Patients Undergoing Definitive Chemoradiotherapy or Radiation Therapy for Locally Advanced Head and Neck Cancer (HUM00078942)

Company or agency sponsoring the study:
Headache & Orofacial Paine Effort Laboratory, Radiation Oncology

Names, degrees, and affiliations of the researchers conducting the study:
Alexandre DaSilva, DDS, DMedSc – Headache & Orofacial Pain Effort Laboratory (H.O.P.E)

1.1 Key Study Information:

You may be eligible to take part in a research study. This form contains information that will help you decide whether to join the study. All information in this form is important. Take time to carefully review this information. After you finish, 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 friends, family, or other doctors about your possible participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you do, be sure you understand what the study is about.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

More than 50,000 Americans (and more than 750,000 people worldwide) are diagnosed with head and neck cancer (HNCa) every year. HNCa impacts oral intake, speech, physical appearance, and emotional well-being. Despite advancements in treatment technology, which improves patient lifestyle and comfort, HNCa patient quality of life (QoL) still suffers. Transcranial Direct Current Stimulation (tDCS) offers a unique pain-relief modality. It is a non-invasive brain stimulation technique, requiring users to wear a specially made cap, which allows for precise stimulation of specific brain areas. tDCS has been shown in other studies, performed by our lab and others, to be safe and effective in several chronic pain conditions, including fibromyalgia, chronic migraines, and multiple sclerosis. The aim of this study is to determine if tDCS can reduce pain perception associated with the effects of receiving chemoradiotherapy or radiation therapy in HNCa patients. As a participant in this study, you will be randomized (like flipping a coin) to one arm of the study or the other. Patients in Arm 1 (chemoradiotherapy/radiation therapy standard of care and tDCS) will receive the tDCS neuromodulation. Patients in Arm 2 (chemoradiotherapy/radiation therapy standard of care alone) will receive the standard of care. The addition of tDCS to your treatment will not affect how the tumor responds to the chemoradiotherapy/radiation therapy you receive, but it may reduce the pain you experience during your treatment.

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?

Patients, between the age of 18-75, with any AJCC stage head and neck malignancy, scheduled for definitive chemoradiotherapy or radiation therapy may participate in this study.
Patients with substantial dementia, patients who are actively being treated for another cancer, or who have any condition that would prevent use of the tDCS (skull abnormality, implanted metal or electronic device, seizure disorder or other neurologic condition) may not fit the criteria for inclusion. Additionally, patients who have taken an investigational drug or device in the last 30 days may not participate.

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

40 patients are expected to take part in this study at the University of Michigan. All subjects will be University of Michigan patients.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

After your initial screening with your Radiation Oncologist, during which eligibility for the study was determined and you were provided with this Informed Consent document to sign, you will be referred to Hospital Dentistry for Evaluation and Clearance (this is performed for all patients as a standard of care). At this time a pre-study visit will be scheduled for before your chemoradiotherapy/radiation treatment begins. At the start of this visit you will be asked to sign the informed consent (if you have not done so already), and only after the informed consent is signed will you complete some questionnaires and an EEG and fNIRS recording will take place. After this appointment you will be randomized into one of the two Arms (those who receive just the Standard of Care, and those you receive the Standard of Care plus tDCS).

You and/or your caregiver will receive on the first week, a proper training with a trained team member regarding remotely supervised tDCS and provided with a study stimulation device and guidelines. You will be real-time supervised via videoconference for these sessions.
According to your decision, you can be treated either totally at the clinic tDCS sessions or combine at home tDCS with at clinic tDCS sessions and can adjust the schedule of sessions (tDCS in clinic or RS-tDCS) at any moment during the study visits.

Participants in both arms will complete the Oral Mucositis Quality of Life and Odynophagia Assessments each of the seven weeks of chemoradiotherapy/radiation therapy, and all pre-treatment surveys will be completed again at a one-week and one-month follow-up visit. Some intraoral (non-identifiable) photographs may be taken over the course of your treatment to help visualize areas of pain you may be experiencing from the chemoradiotherapy/radiation therapy.

<u>Trasncranial Direct Current Stimulation (tDCS):</u>
tDCS is a method of non-invasive brain stimulation that is based on the application of a weak direct current to the head that flows between two relatively large electrodes—anode and cathode. You will participate in one tDCS trial, consisting of tDCS stimulation and surveys. The tDCS will occur on the day of your chemoradiotherapy/radiation therapy. This will last the seven weeks of your chemoradiotherapy/radiation therapy. We will combine remotely supervised tDCS sessions to facilitate participants' compliance and retention during multiple visits.

You will participate in a total of 20 tDCS sessions, each lasting approximately 45-60 minutes, including examination, set-up, clean-up, pain/mood questionnaires, and a tDCS Side Effects Questionnaire. During each tDCS session, two

electrodes will be placed on your head using a specialized cap. 2 mA of transcranial direct current stimulation will be applied for 20 minutes. Before, during and after select active tDCS sessions, EEG data will be recorded. In addition, two pain questionnaires and one mood questionnaire—Short-Form McGill Pain Questionnaire, HOPE Pain Assessment Form (GeoPain), and Positive and Negative Affect Schedule—will be completed before and after each tDCS session.

If a stimulation appointment cannot be completed on a scheduled day, then two stimulations will take place the day before or following day. The first stimulation will be in the morning, and the second stimulation will take place in the afternoon.

EEG (Electroencephalography):
EEG is the recording of electrical activity along the scalp, measuring voltage fluctuations and electrical activity over a short period of time. This is recorded from multiple electrodes placed on the scalp. The tDCS system we use, Starstim by Neuroelectrics, allows us to use the same cap to simultaneously administer tDCS and record EEG readings. Simultaneous tDCS/EEG evaluation of cortical mechanisms can elucidate valuable information regarding the immediate tDCS effects on the brain.
During the study, EEG recordings will be taken at the pre-study visit, the initial stimulation, last stimulation on first week, and the fifth and seventh week of treatment (both on the last session on week), as well as the one-week and one-month follow-up visit for participants in both arms of the study.

Summary of what will happen to you during the study: *(tDCS arm only)*

- Pre-treatment Visit: EEG recording, fNIRS recording and questionnaires
- Week 1: Questionnaires
- Weeks 2 and 3: Daily (5x per week) tDCS, two EEG recording at week 2, one fNIRS recording at first session, questionnaires
- Weeks 4 and 5: 3x per week tDCS, one EEG recording at week 5, questionnaires
- Week 6 and 7: 2x per week tDCS, one EEG recording at week 7, one fNIRS recording at last session, questionnaires
- One-week follow-up visit: EEG recording, questionnaires
- One-month follow-up Visit: EEG recording, questionnaires

4.2 How much of my time will be needed to take part in this study?
Typically, as a standard of care, a course of radiation lasts 6-7 weeks and treatments are delivered each day, Monday through Friday, each week. Each radiation treatment lasts approximately 10-20 minutes.

Cisplatin or carboplatin infusion will require a couple hours once weekly during this time period.

Patients receiving tDCS will undergo the intervention on the day of their chemoradiotherapy/radiation therapy appointments and will last 45-90 minutes. This time period includes: 20 minutes for tDCS stimulation, a period of time before and after stimulation for EEG and fNIRS recording (if required during that visit), time for allotted surveys required on that visit, clean-up, and transportation to and from the location and Radiation Oncology. You will be escorted to and from Radiation Oncology by a study team member.

The participants and/or his/her caregiver will receive, during the first week, a proper training with a trained team member regarding remotely supervised tDCS, that will last 45-60 minutes.
Control patients not receiving tDCS will be given questionnaires prior to their radiation therapy appointments. On days where EEG and fNIRS readings are required, patients will be similarly escorted to and from the research site within the hospital by a research team member. EEG and fNIRS appointments will last one-hour, which includes the EEG recording, completion of questionnaires, clean-up, and transportation.

Follow-up visits last about 1 hour each, which allows for EEG recording, questionnaire/survey completion, and transportation time.

4.3 When will my participation in the study be over?
After your chemoradiotherapy/radiation therapy treatment is complete, you will return for a one-month follow-up appointment, then every 2 months during years 1 and 2, and at 3-month intervals during year 3. Your participation in the study will **end after the one-month follow-up visit**.

4.4 What will happen with my information and/or biospecimens used in this study?
Your biospecimens and collected information may be shared with M-Cubed (a research program within the University of Michigan).

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

Your identifiable private information or identifiable biospecimens 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 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:

1) Loss of confidentiality around sensitive information:
To minimize risk: You will be assigned research numbers, and all research information collected will be linked to you only by this number. Great care is taken to remove all identifying information from research records. A single tracking file contains links to the research records and subject codes. Recruitment tracking files are kept only for the duration of the study. Paper records are kept in locked file drawers in a locked room, which only authorized research personnel have access. Paper records with identifying information (consent form, payment records) are kept in locked file cabinets, physically separate from the research records. Computer records with identifying information are kept on secure, password protected servers. Staff is trained to scrupulously protect the confidentiality of sensitive information, and take care to limit the printing of documents with identifying information and to avoid unnecessary discussion of subject names.

2) Transcranial Direct Current Stimulation (tDCS):

In general, tDCS is a safe procedure, although it is not approved by the FDA for any treatment. In more than 30 published research studies involving hundreds of participants, no serious or long-lasting side effects have been reported. The most common adverse effects are tingling during application (not common), redness in the area of stimulation and dizziness at the beginning and end of the session. To minimize the occurrence of these adverse events we will increase the current very slowly at the beginning and decrease very slowly at the end of the stimulation to avoid dizziness. In addition, we will use a saline solution to decrease the tingling sensation.

The participants will be instructed to abort the neuromodulation session at-home (RS-tDCS) if reports significant discomfort or other adverse event, otherwise needs to discontinue a session, or if study staff determines that the session should be discontinued. In addition, the study will be made aware of the proper designated “stop criteria”. If the “stop criteria” will be met at any time throughout the study, the session and/or ongoing study participation will be reviewed.

The Starstim® used to deliver tDCS has built-in safety measures. It is a battery-powered device, blocking any hazardous contact with the electrical power grid. It will not operate if the contact impedance is too high, indicating a bad electrode contact, and it cannot stimulate while connected to the grid for charging.

3) EEG:
The EEG has been used for many years and is considered a safe procedure. The test causes no discomfort. The electrodes only record activity and do not produce any sensation. In addition, there is no risk of getting an electric shock. There is only a slight risk of irritation of the scalp where the electrodes are placed

We do not anticipate negative side effects as a result of these procedures; however, it is possible that you may have an unexpected reaction. Participation in multiple studies may be hazardous to you. If you are already participating in another study, please inform us before you are enrolled in this study. If you are or may become pregnant during the study, please inform us prior to enrollment.

4) fNIRS
There are no known risks with the use of fNIRS. It is an important tool for clinical monitoring of tissue oxygenation and measurement of cortical activity, thereby appear that an advancement in brain imaging. fNIRS will take at the pre-study visit, at the first stimulation visit, at the fifth week and the last stimulation visit, during the neuromodulation session in clinic.

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, for instance, the study will be made aware of the designated "stop criteria". 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 other than to help advance scientific knowledge. Participants in this study may experience pain relief as a result of the tDCS treatments.
However, it is possible that some participants will not have extended reduction of pain. We hope this will help us to better understand ways to treat chronic pain conditions.

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?
Your participation in this project is voluntary, and participation will not help in treatment or diagnosis of any medical condition. The alternative to experiencing these procedures is not to participate. You should feel free to choose or reject this study or to withdraw from any portion of this study at any time without penalty or loss of benefits to

which you may otherwise be entitled. The physicians and other staff of the University Hospital will continue to offer their best medical care regardless of your decision. You may want to discuss additional treatment options with the study team or your current physicians.

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" (below).

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

There is no inherent risk in leaving the study early.

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 my health plan or I be billed for any costs of the study?

There are no costs or billing for this study.

The study team has given you instructions about this research study. It is important that you follow these instructions carefully. If you get sick, have a medical complication, or are injured as a result of your being in the study, call Dr. Eisbruch immediately at 734-936-4300, or Dr. Alexandre DaSilva at 734-615-9390. The doctor will either treat you or send you to another doctor for treatment. You will get free medical care at the UMHS for any complication, injury, or illness caused by the study device or procedure. The UMHS and the study doctor are responsible for determining whether your condition was the result of your participation in the study. The UMHS will pay for your treatment only if the need for treatment has been caused by the study device or procedure. This means that you or your health plan must pay for any treatment that is part of your usual medical care or that is related to a medical condition you had before participating in the study. It is not the general policy of the federal funding agencies to compensate or provide medical treatment for human subjects in federally funded studies.

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?

No, you will not be paid for taking part in this study. There may be funds available to help assist you with costs associated with travel for this study, if the study team is unable to arrange a visit that coincides with a previously scheduled hospital appointment. This will include reimbursement, in cases of financial hardships and extenuating circumstances only, for gas, mileage, and hotel stay if necessary. Discuss this with the study team. All reimbursement will be made at the discretion of the primary investigator.

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

The University of Michigan is an owner and Dr. DaSilva is an inventor of a tool being used in this research. This means, the University of Michigan and Dr. DaSilva might one day profit from the tool.

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 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?

We shall put the information collected about you during the study into a research record. This research record will not show your name, but will have codes entered in it, that will allow the information to be linked to you by the investigators. However, we shall keep your research record confidential, to the extent provided by federal, state and local law. We shall not allow anyone to see your record, other than people who have a right to see it. You will not be identified in any reports on this study. Nevertheless, the National Institutes of Health, the United States Federal Food and Drug Administration, and the Institutional Review Board monitoring this study may inspect the records of this investigation.

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 condition, the treatment you have received, and your response to the treatment
- 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 or presented at a scientific meeting, but would not include any information that would let others know who you are.

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.

9.3 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.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 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:	Alexandre DaSilva, D.D.S.; D.Med.Sc.
Mailing Address:	University of Michigan Dental School 1011 N. University Ann Arbor, MI 48109-0720 adasilva@umich.edu
Telephone:	(734) 615-9390
Pager:	16582
Research Staff:	Paul Swiecicki, MD
Mailing Address:	University of Michigan Medical School Department of Internal Medicine/Hematology and Oncology

Ann Arbor, MI 48109
pswiecic@umich.edu
Telephone: C/O (734) 615-9390

You may also express a 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: US Country Code: 001)
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

Consent to Participate in the Research Study (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 [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): _____

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): _____

Witness (optional)

I observed the above subject (or his/her legally authorized representative, if applicable) sign this consent document.

Printed Legal Name: _____

Title: _____

Signature: _____

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