You Are Being Asked to Be in a Research Study
Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study you will be one of about 70 people who are being studied, at Emory.

Why is this study being done?
This study is being done to help us find out how the brain processes pain signals in people who experience temporomandibular disorder (TMD), which involves chronic pain in the jaw and/or face, in their everyday life. You are being asked to be in this research study because the way you process pain may help us better understand pain processes in people with chronic pain.

Do you have to be in the study?
It is your decision to be part of this research study. You do not have to be in it. Your choice will not affect your access to medical care for your condition. Before you make your decision, you should take time to learn about the study.

What do I have to do if I choose to participate in this study?
If you are eligible and want to be part of the study, you will participate for 7 hours (1-2 study visits). The researchers will ask you to do the following. Complete questionnaires regarding your medical history, mood, and pain, if applicable, and rate the intensity, painfulness, and/or unpleasantness of pressures, sounds, images, and temperatures applied by sensory testing devices. You will be asked to complete an MRI screening form before undergoing an MRI scan of your brain. If you are a woman of child-bearing potential, you will be asked to take a urine pregnancy test prior to the MRI. ALL of these procedures will be paid for by the study.

How is this study going to help you?
If you are in the study, you will be helping the researchers answer the study questions. There are no direct benefits to participants. This is not a treatment study and your choice to participate (or not) will not affect your clinical care.

What are the risks or discomforts I should know about before making a decision?
The study will take time. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious – for this study, discomforts include mild-to-moderate pain sometimes lasting minutes from some of the sensory testing, and being asked to lie completely still in an MRI scanner for up to an hour and a half. More serious risks, while rare, could include loss of privacy and breach of confidentiality. A full list of expected risks, their frequency and severity are in the "What are the possible risks and discomforts?" section of this document.

Alternatives to Joining This Study
Since this is not a treatment study, the alternative is not to participate.

Costs
You WILL NOT have to pay for any of the study procedures. Participation in this study will NOT pay for any of your medical procedures.

What Should I Do Next?
Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions (e.g., about exact time commitment, about unfamiliar words, more details on specific procedures, etc.). Take time to consider this, and talk about it with your family and friends.

Emory University
Consent to be a Research Subject / HIPAA Authorization

Title: Central and Peripheral Factors in Temporomandibular Disorder (TMD)

Principal Investigator: Daniel Harper, PhD, Department of Anesthesiology, Emory University

Study-Supporter: National Institutes of Health

Introduction

You are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.** The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:

- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form, you will not give up any legal rights.

What is the purpose of this study?

We are investigating people who experience chronic pain in the head and/or face in their everyday life. We are using unique tests to help us find out how the brain processes chronic and acute pain messages. We will observe people to see how pain and sensory processing differs in TMD. This is not a treatment study and will not attempt to improve your symptoms with any type of therapy, medication, or diagnostic procedure.

What will I be asked to do?

Questionnaires: You will be asked to complete numerous questionnaires that ask you about your current or past pain and mood symptoms. These take most people less than one hour to complete. This will occur at Visit 1.
Height and Weight: Your height and weight will be obtained to make sure that you can be comfortable within the MRI scanner.
Urine Pregnancy Test: If you are a female of child-bearing potential, we will ask you to give us a urine sample so that we can make sure you are not pregnant because the risks of an MRI scan to an unborn fetus are unknown.
Pressure Sensitivity (Algometer) Evaluation: This test is designed to assess how sensitive you are to pressure pain. You will have a pressure test with a handheld "algometer", which the experimenter uses to apply pressure with a rubber probe to your face/jaw, trapezius, and forearm. Pressure will be gradually increased until you press a button indicating that you first feel pain, at which time the pressure will be released. This test will be repeated up to three times at each site. This procedure will last about 15 minutes.
Auditory Sensitivity Evaluation: We will first screen you for potential hearing loss in each ear using an "audiometer" that presents sounds to your ears using headphones. We will then test your auditory sensitivity by having you listen to pure tones (like beeping sounds) of different volumes and then having you give us numbers that describe how loud and unpleasant the sounds were to you. These procedures take about 30 minutes or less to complete.

Cuff Pressure Sensitivity Evaluation: This test will assess how sensitive to muscle pain you are. For this assessment, we will have you either lie down or remain in a seated position in a chair with your foot resting on a support at a slightly elevated position. We will attach an inflatable cuff (similar to a blood pressure cuff) to your lower leg just below the knee. We will then inflate the cuff for brief periods (≤10 seconds) to determine your sensitivity to a range of different pressures. We will also find a pressure that you find tolerable for a more extended period of time, which we will test later in the MRI scanner, applying repeated stimuli (< 25 seconds) with short breaks in between. We will do cuff pressure sensitivity testing both in and outside of the MRI scanner.

Thermal Sensitivity Evaluations: Your sensitivity to thermal stimuli, including warmth, coolness, painful heat, and painful cold will be assessed on your hands, forearm, and jaw/face. This will be performed using several different devices, most of which are under computer control. Like the pressure sensitivity measurements, in some cases we will change the temperature and have you tell us when you feel a certain sensation, and in other cases we will ask you for ratings describing the perceived thermal intensity, pain, and/or unpleasantness of the thermal stimuli. In one test you will be asked to rest your hand and/or forearm on thermal bars for a period of time (~2 minute) before we apply different thermal stimuli to your opposite arm or hand. During the thermal testing, you will experience temporary discomfort and pain from feeling cold or hot stimulation of your skin. This will go away almost immediately after the stimuli are removed. We will do some thermal testing both in and outside of the MRI scanner.

Visual Sensitivity Evaluation: During this test, you will be asked to stare at visual stimuli on a computer screen. There will be various flashing patterns with different frequencies and levels of brightness, and you will be asked to rate the intensity and unpleasantness of these stimuli. We will do visual testing both in and outside of the MRI scanner.

***fMRI* Evaluation:** We will use Magnetic Resonance Imaging (MRI) to assess the structure, function, and neurochemistry of certain regions of your brain. Functional MRI is a research method that makes it possible to observe changes in activity within the brain in response to various stimuli like pressure, which we record and analyze, and it is based on the standard MRI technique. This component of the study involves lying on a table that is then moved into a hollow machine (the magnet). For all fMRI scans, you will lie in the scanner with a magnetizing coil surrounding your head. This coil is a device that secures your head in a stable position and allows the magnet to obtain clear images of the anatomy of your head and the blood flow and change of chemicals in your brain. For some fMRI scans, we will ask you to undergo certain tasks (e.g. cuff pressure, heat, or visual sensitivity) while you are lying in the scanner to see how your brain changes while processing pain. You will be asked to lie very still on your back in the scanner for up to 90 minutes. The MRI will normally occur on the same day as the other testing, unless your preference is to have the MRI on a separate day (e.g. you can only participate for half days).

*****TMD PATIENTS ONLY*****

Take-Home Diary : If you are a TMD patient, you will be asked to report pain ratings 5 times a day for 2 weeks following completion of your in-person participation. You will be provided with a self-addressed stamped envelope to return the diary, or there will be an option to submit your responses electronically.

Follow-Up Questionnaires: If you are a TMD patient, we will contact you by phone and/or email at 3, 6, and 12 weeks following your in-person participation to inquire about your current pain levels, your jaw function, and some other information similar to the questionnaires you completed on your initial visit. You will be able to give a research team member this information over the phone, or you will be given a link to respond to the questions online. This should take less than 20-30 minutes per follow-up.

Who owns my study information and samples?

If you join this study, you will be donating your samples and study information. You will not receive any compensation if your samples or information are used to make a new product. If you withdraw from the study, data and samples that were already collected may be still be used for this study.

What are the possible risks and discomforts?

There may be side effects from the study procedures that are not known at this time.

Sensory Testing: The most common risks and discomforts expected in this study are pain and discomfort during some of the sensory testing. Because the nature of this experiment involves the invocation of pain, we expect that pain and discomfort will be very common during some of the pressure and thermal sensitivity evaluations. We also expect some discomfort during some of the visual and auditory sensitivity testing. Given this necessity, we will take measures to minimize the long-term effects of the pain caused during this study. You may experience temporary dizziness in the minutes following the visual task. We have selected temperature, volume, and pressure ranges that are not capable of causing permanent damage during the short time the stimuli will be applied. The risk of injury is rare. These or similar sensory testing procedures have been used in numerous studies across the world, and the PI (Dr. Harper) has over 15 years of experience doing sensory testing in people with and without chronic pain with no serious adverse events. Following the pressure sensitivity evaluations using the algometer and the cuff, there is a possibility of short-term tenderness or reddening of the skin in the minutes following the examinations. There is also a risk of mild, transient bruising associated with inflation of the cuff, which is estimated to occur in less than 5% of cases. The researchers who will be conducting these tests have been educated in how to perform these tests safely. You may stop the tests at any time if the testing becomes too painful, too uncomfortable, or for any other reason, and the stimulus will be removed at once. While unlikely, if you experience any hearing sensitivity or ringing in your ears following the auditory testing, this should go away in a short period of time. During the visual task, you may experience some temporary discomfort or sensitivity from the flashing patterns that are displayed. There is a minimal risk that this task may cause headache or nausea. You may stop these tests at any time if they become too uncomfortable.

Questionnaires: The less common risks and discomforts expected in this study include the possible discomfort associated with being asked personal questions about your health history. You may refuse to answer any question on the questionnaires or surveys that may be uncomfortable. The research staff will be available to help you if needed.

Magnetic Resonance Imaging (MRI): There are known risks to the magnet's ability to pull metal objects toward it. This pull can cause metal objects in the body (e.g., surgical clips or staples) to move, causing bleeding or disruption of surrounding tissue. Metal objects carried or worn by a person (e.g., jewelry, hair clips, tools) can be pulled toward the magnet; if they are free to fly through the air there is the danger that someone could get hurt if the moving object struck them. The MRI can cause pacemakers or stimulators implanted in the body to malfunction. There is also a risk that metallic objects in or on your body (e.g., medicated skin patches) may be heated by the radio waves, possibly causing burns. To ensure your safety for the MRI procedure you will be asked to bring or wear clothing without metal fasteners, and remove jewelry and any other metal objects from your body. We will also assess whether metallic objects that may be implanted (e.g., surgical clips or staples, pacemakers) are hazardous or acceptable. If allowed, skin patches may be removed for the scan. The MRI scanner is tunnel-shaped and has a diameter of about one and one-half-feet. There is a minor risk of discomfort or anxiety from being in the confined space of the MRI scanner. There is also a risk of discomfort from lying still in the scanner. We will provide pads and blankets to make you as comfortable as possible while lying in the scanner. It is extremely important that you lie still throughout the MRI procedure. You will be able to talk to us throughout the MRI study, and you will be able let us know right away if you want to stop the study and get out of the scanner. The investigators will be sitting in the control room and in the MRI-suite, present at all times. The MRI produces rhythmic and loud noises. There is a possible risk of ringing in your ears after fMRI scanning. You will wear earplugs and/or headphones to reduce the loud noises made by the scanner. Some studies, like this one, have the potential to cause "peripheral nerve stimulation" (PNS). PNS is a light touching sensation on the skin surface, lasting only for a few seconds. It may cause mild discomfort, but is not harmful to you. The MRI machine is operated within FDA guidelines so the potential for inducing PNS is low.
The type of imaging used in this study is for research purposes only. It is not meant to diagnose illnesses, find tumors, or pick up any other defects in your brain. However, there is still a chance that this MRI could show a defect that is already in your brain, such as a cyst or tumor. Many such defects are not important, but you may want to look into them further. If the researchers were to observe something on the MRI scan that they felt warranted following up on, they would tell

you what was observed in the research scan and let you decide whether or not to follow up with a physician and potentially undergo a clinical MRI scan.
No adverse effects from the static magnetic field have been reported in people. However, there may be unknown risks.

If you are a woman: to protect against possible side effects of the study procedures, women who are pregnant or nursing a child may not take part in this study. The risks of an MRI on pregnant women and fetuses are not yet known. If you are pregnant, there may be risks to you, the embryo, or fetus. If eligible, you will also be offered a urine pregnancy test immediately prior to the fMRI scan. You may refuse the pregnancy test; however, if you do and you are of childbearing potential, you will be unable to go into the scanner.

If you are a man: the effect of MRI on sperm is not known. To protect against possible side effects, if you are a man you should not get a sexual partner pregnant for 1 day after the MRI scan. You and your doctor should agree on a method of birth control to use throughout the study.

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Will I benefit directly from the study?

This study is not designed to benefit you directly. This study is designed to learn more about chronic pain conditions, and the study results may be used to help others in the future.

Will I be compensated for my time and effort?

You may be compensated using gift cards or our preferred method of compensation called ClinCards. All payments are made using a personal payment card. We issue this to you for free. The payment card is a prepaid debit card. It can be used exactly like a MasterCard. We load money onto your card electronically every time you need to be paid. ClinCards are managed by by Greenphire, an independent company specializing in payments for research studies and clinical trials. To issue your card, we need to give Greenphire some of your personal information. Banks and other financial institutions can access this information if they need to verify your identity when you use your card.

For TMD patients only: If you meet eligibility criteria and complete additional follow-up phone calls and surveys, you will receive an additional $110 via gift cards or ClinCard to compensate you for your efforts and time.

If you do not finish the study, we will compensate you a prorated amount for the tasks you have completed.

Emory University is required by law to report any payments we make to the IRS. Research payments in cash or cash equivalents that exceed $600.00 per calendar year must be reported to the Internal Revenue Service (IRS) by the University. The level of reimbursement for this study is at a level that the potentials exist for the federal tax reporting to the IRS for your participation in this study. To do this, Emory University Department of Finance needs to keep your Social Security Number on file. We are asking you to allow us to communicate your name, address, date of birth, research study name and Social Security Number to Greenphire and Emory University Department of Finance. If you want receive e-mail or text alerts when payments are made to you, we will ask you to provide your e-mail or phone number as well. As all of this information will be stored on computers owned by Greenphire. Greenphire will not have access to any other information collected during this study. Full instructions about using your card are included when we issue it. Please ask if you have any questions or concerns about the card scheme. You can decline payment if you are concerned about confidentiality.

Each of your study tasks will be prorated according to the table below. Please let us know if you have any questions regarding the compensation table.

Test Procedures	**Duration (hours)**	**Compensation**
Questionnaires Sensory Testing MRI	1.0 4 2.0	$30 $90 $70
TMD ONLY: Symptom Report Follow-Up (take home or survey link)	14 days	$50
TMD ONLY: Follow-up phone call or survey link ($20 each)	0.33	$60
Maximum Compensation		**$300**

What are my other options?

Your participation in this study is voluntary. There are no treatments in this study. You may contact your doctor to discuss treatment options you may have.

How will you protect my private information that you collect in this study?

Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Certificate of Confidentiality

There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory from making the following disclosures about you:

- Giving state public health officials information about certain infectious diseases.
- Giving law officials information about abuse of a child, elderly person or disabled person.
- Giving out information to prevent harm to you or others.

Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

Storing and Sharing your Information

De-identified data from this study (data that has been stripped of all information that can identify you), including your de-identified neuroimaging, questionnaire, and sensory testing information, may be placed into public databases where,

in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Your data and specimens from this study may be useful for other research being done by investigators at Emory or elsewhere. To help further science, we may provide your de-identified data and/or specimens to other researchers. If we do, we will not include any information that could identify you. If your data or specimens are labeled with your study ID, we will not allow the other investigators to link that ID to your identifiable information.

In general, we will not give you any individual results from the study of the samples you give us. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

You will also have the option to agree to be contacted for potential studies in the future. If you consent to this option, we will keep your name, contact information (e.g. phone, email address, etc.), other demographic factors like age and gender, and your clinical status (i.e. if you are a chronic pain patient) in a password protected spreadsheet indefinitely. Access to this spreadsheet will only be available to the PI or his designees. Individuals who have consented for this option may be contacted by a member of the PI's research team for follow-up studies or other studies for which you might qualify and be interested in participating in. Opting into this option does not mean you are consenting now to participate in the future. Instead, it gives us the ability to contact you in the future to determine if you may be interested in an additional studies. If you were to be interested, there would be a separate informed consent process to take place before enrollment into those studies.

Medical Record

If you have been an Emory Healthcare patient before, then you already have an Emory Healthcare medical record. If you have never been an Emory Healthcare patient, you do not have one. An Emory Healthcare medical record will be made for you if an Emory provider or facility gives you any services or procedures for this study.

Copies of the consent form/HIPAA authorization that you sign will be put in any Emory Healthcare medical record you have now or any time during the study. The confidentiality of the study information in your medical record will be protected by laws like the HIPAA privacy rule. State and federal laws may not protect the research information from disclosure.

The results of the study tests and procedures will be used only for research purposes and will *not* be placed in your medical record.

Tests and procedures done at non-Emory places may not become part of your Emory medical record. Also, if you decide to be in this study, it is up to you to let your other health providers know.

In Case of Injury

If you believe you have become ill or injured from this research, you should contact Daniel Harper, PhD, at 404-727-7789 or daniel.harper@emory.edu. You should also let any health care provider who treats you know that you are in a research study.

If you get ill or injured from being in the study, Emory will help you to get medical treatment. Neither Emory nor the sponsor will pay for your medical treatment. Your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurance does not pay, then you will have to pay these costs.

Emory and the sponsor have not, however, set aside any money to pay you if you are injured as a result of being in this study or to pay for this medical treatment. For Emory, the only exception is if it is proven that your injury or illness is directly caused by the negligence of an Emory employee. "Negligence" is the failure to follow a standard duty of care. You do not give up any legal rights you may have by being in this study, including any right to bring a claim for negligence.

Costs

There will be no costs to you for participating in this study, other than basic expenses like transportation and parking. You will not be charged for any of the research activities. If the study procedures result in any medical complications that would not fall under "injury" as discussed above, the cost of treatment for those complications may be charged to you or your insurance.

Withdrawal from the Study

You have the right to leave this study at any time without penalty.

The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

These are the possible reasons why the researchers may stop your participation:

Failure and/or inability to follow instructions
Study procedures appear to be causing discomfort/stress beyond what is anticipated
Difficulty contacting you and scheduling follow-up sessions (for TMD patients)

In the event that you decide to discontinue your participation before the study is complete, we may ask you for a reason why you have decided to discontinue your participation so that we can report that information to the IRB and/or study sponsor. You are free to not provide a reason if you do not wish to do so, in which case we may report that your participation was discontinued for "no reason provided by participant".

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI for the main study and for any optional studies in which you may choose to participate.

Main Study

PHI that Will be Used/Disclosed:

The PHI that we will use or share for the main research study includes:

- Medical information about you including your medical history and present/past medications.
- Results of tests you have before, during, or after the study that are directly related to your chronic pain condition, like MRIs or CT scans of your jaw.
- Laboratory test results.

Purposes for Which Your PHI Will be Used/Disclosed:

We will use and share your PHI for the conduct and oversight of the research study. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, the Georgia Clinical and Translational Science Alliance (CTSA), and the Institutional Review Board (IRB). If you leave the study, we may use your PHI to determine your health, vital status or contact information.

Use and Disclosure of Your Information That is Required by Law:
We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults.

Authorization to Use PHI is Required to Participate:
By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form.

People Who will Use/Disclose Your PHI:
The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your PHI to conduct the study.
- The Principal Investigator and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.
- The Georgia Clinical and Translational Science Alliance (CTSA) staff will use and disclose your PHI to conduct clinical study procedures such as urine pregnancy testing.
- The NIH is the Sponsor of the study. The Sponsor may use and disclose your PHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your PHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- The following people and groups will use your PHI to make sure the research is done correctly and safely:
    - Emory offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Other researchers and centers that are a part of this study.
    - Government agencies that regulate the research including: Office for Human Research Protections.
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your PHI may be shared with that new institution and their oversight offices. PHI will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

Optional Permission to Contact for Future Studies:

Authorization for This Use of PHI is Required to Participate in Optional Study, but Not in Main Study:
You do not have to authorize the use and disclosure of your PHI for the optional studies. If you do not authorize the use and disclosure of your PHI for the optional studies, then you may not participate in the optional research study, but you can still be in the main research study.

Additional People Who Will Use/Disclose Your PHI for Optional Study:
The following people and groups will use and disclose your PHI in connection with the optional research study: The Principal Investigator (Dr. Harper) or his designee(s), and the Georgia CTSA.

Expiration of Your Authorization
Your PHI will be used until this research study ends.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact the study team at: Dr. Daniel Harper, 101 Woodruff Cir. Room 7303, Atlanta, GA 30322.

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly and the data is correct. If you revoke your authorization you will not be able to stay in the main study.

If you revoke your optional authorization to contact you for potential future studies, your name and other information will be removed from the spreadsheet in a reasonable amount of time and you will not be contacted for potential participation in future studies.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them.

To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information

- Contact Daniel Harper, PhD (Principal Investigator) at 404-727-7789 or daniel.harper@emory.edu If you have any questions about this study or your part in it,
- If you feel you have had a research-related injury,
- If you have questions, concerns or complaints about the research

Contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu:

- If you have questions about your rights as a research participant.
- If you have questions, concerns or complaints about the research.

You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

Consent and Authorization

You are also free to agree or disagree to the option below:
In the boxes below, please check the box under yes if you agree to the statement and no if you do not agree and then initial on the appropriate line below:

[Permission to be Contacted for Additional Studies] _____Initials

Yes ☐

I DO agree to be contacted in the future regarding participation in other research studies. I understand that I may then decide if I am willing to participate.

No ☐

I DO NOT agree to be contacted in the future regarding participation in other research studies.

TO BE FILLED OUT BY SUBJECT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in this research study, and any optional studies you initialed above. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

_____
Name of Subject

_____ _____ **AM / PM**
Signature of Subject (18 or older and able to consent) **Date** **Time**

TO BE FILLED OUT BY STUDY TEAM ONLY

_____
Name of Person Conducting Informed Consent Discussion

_____ _____ **AM / PM**
Signature of Person Conducting Informed Consent Discussion **Date** **Time**