CANDESARTAN'S EFFECTS ON ALZHEIMER'S DISEASE AND RELATED BIOMARKERS (CEDAR)

NCT02646982

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IRB0008454

You Are Being Asked to Be in a Research Study

What Is a Research Study?

The main purpose of research studies is to gain knowledge. This knowledge may be used to help others. Research studies are not intended to benefit you directly, though some might.

Do I Have to Do This?

No. Being in this study is entirely your choice. If you decide to join this study, you can change your mind later on and withdraw from the research study.

Taking part in a study is separate from medical care. The decision to join or not join the research study will not affect your status as a patient.

What Is This Document?

This form is an informed consent document. It will describe the study risks, procedures, and any costs to you.

This form is also a HIPAA Authorization document. It will describe how your health information will be used and by whom.

Signing this form indicates you are willing to take part in the study and allow your health information to be used.

What Should I Do Next?

1. Read this form, or have it read to you.
2. Make sure the study doctor or study staff explains the study to you.
3. Ask questions (e.g., time commitment, unfamiliar words, specific procedures, etc.)
4. If there will be medical treatment, know which parts are research and which are standard care.
5. 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: Effects of Candesartan on Alzheimer's Disease and Related Biomarkers

Principal Investigator: Ihab Hajjar, MD

Sponsors: Alzheimer's Disease Drug Foundation (ADDF) and The National Institute 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.

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 may search this Web site at any time.

Study Overview

What is the purpose of this study?

This study is intended to investigate the effect of candesartan, a blood pressure medication, on cognitive function and thinking skills in those who have early or mild memory difficulties, also called mild cognitive impairment or MCI. This study also aims at studying the effect of candesartan on the build-up of specific proteins in the brain termed Amyloid and Tau. Amyloid and Tau protein build up may lead to Alzheimer's disease.

Who is eligible to participate?

To be eligible for this study you need to:

- be 50 years and older;

- have early or mild memory difficulties, also called MCI. We will test your thinking skills when you come to the study center;
- have a blood pressure (BP) that is 110/40 mmHg or greater. You cannot have a diagnosis of hypertension or be receiving blood pressure medications unless it is given to you for reasons other than hypertension;
- your kidney function, potassium level, platelet counts and bleeding tendency should be within a normal range;
- In addition, to be eligible we need to check if you have protein build-up in the brain. To do that, we will obtain a sample of the fluid that surrounds the brain, also called cerebrospinal fluid or CSF for short. CSF can be obtained using a routine procedure called lumbar puncture or spinal tap. If the CSF shows signs of protein build-up, then you would qualify for the study. If it does not show signs of protein build-up, then you will not qualify for the study.

Your doctor may have already performed this CSF analysis. In that case, we do not need to redo the spinal tap to check if you qualify for the study and we would like to obtain these results from your doctor to see if you are eligible. You will still need to have a spinal tap as part of the study at the baseline visit or if we could not obtain the CSF analysis from your doctor.

If your blood pressure becomes elevated during the study period and your physician recommend starting a blood pressure medication, it is very important to notify us of this as soon as possible. For your safety it is important to let your physician know that you are possibly receiving candesartan before starting any blood pressure medicine.

We ask you to call us before starting any new medication in order to ensure your safety. Some medications should not be used in combination with the study medicine, candesartan. These include: angiotensin converting enzyme inhibitor (ACEI) such as Lisinopril, Captopril, Enalapril, Moexipril, Perindopril, Quinapril, Ramipril or Trandolapril; angiotensin receptor blockers (ARB) such as Losartan, Candesartan, Eprosartan, Irbesartan, Olmesartan, Telmisartan, and Valsartan; renin inhibitors such as Aliskiren; or Lithium. If your physician recommends any of these drugs and you wish to start on it, then we will need to withdraw you from the study to maintain your safety.

We plan to enroll 72 individuals for this trial. Of those 72 participants, we will select a subgroup of participants to undergo specialized nuclear imaging also called PET scans. We will ask the same subgroup who complete the PET scans to undergo a retinal scan and eye tracking evaluation.

What will I be asked to do?

If you are eligible and you decide to take part in this study you will sign this informed consent form and you will be enrolled in this study for 1 year. You will need to take candesartan at 8, 16 or 32 mg once a day or a similar placebo. A placebo is an inactive medication. There is 50% chance you will receive candesartan or placebo.

Your participation in the study involves coming to the study center for interviews, brain scans, a lumbar puncture (also called a spinal tap), blood pressure monitoring and blood tests. You will be asked to visit the study sites at least 8-11 times during that year. The following describes what happens at each visit:

Screening Visit:
During the screening visit, we will ask you to sign this informed consent. We will measure your blood pressure, review the medications you are taking, and ask you a set of questions regarding your medical history. You will have memory and cognitive function tests and a blood sample will also be drawn to check on your eligibility for this study. A blood sample (2-3 Tablespoons) will also be drawn to measure the number of stem cells in the blood, the degree of inflammation and genetic profiles. You will also be asked to bring all of your prescribed medication bottles.

During this visit we will also make sure that you understood the details of the study so you can make an informed decision to participate. If you are having trouble with the details of the study, we will ask for a surrogate and study informant to act on your behalf. The surrogate may be your legal guardian, next of kin, or familial caregiver. If you do not need a surrogate or study informant to act on your behalf, we will still need a friend or family member to offer information about your memory for one of our questionnaires during the study. That person will also need to consent to the study.

If you qualify then a spinal tap or lumbar puncture will be performed. Lumbar punctures will be performed by a trained physician, nurse practitioner or physician assistant. If a spinal tap has already been performed and the protein build-up has already been checked by your doctor, then we don't need to repeat it at this visit.

What is a lumbar puncture?
A lumbar puncture, also called a spinal tap, is a procedure to obtain a sample of fluid (also called cerebrospinal fluid or CSF) that surrounds the brain. It will be performed twice during the study period. We will ask you not to eat or drink anything except water for at least 6 hours prior to having the spinal tap done.

It is a routine procedure in many clinical and hospital settings. To obtain the fluid we need to insert a small needle to obtain the spinal fluid from the lower back. For this lumbar puncture, you will be asked to lie on your side with your knees drawn as close to the chest as possible or to sit with your arms and head resting on a table. Your lower back will be cleaned then numbed with local anesthetic, such as lidocaine. Lidocaine will help reduce pain sensations that may be caused by this procedure. A thin needle (typically 3.5 to 4 inches long) will be introduced into the back space between the backbones. About 2-3 teaspoons of spinal fluid will be removed and the needle withdrawn. If no spinal fluid is obtained on the first attempt, a second attempt will be made following the same steps. This lumbar puncture procedure will take approximately 20-40 minutes. After the lumbar puncture is completed, you will lie on your back for about 10-15 minutes. The spinal tap can be done on the same visit as your other study visits or on a separate visit. You should avoid any strenuous physical activity for the next 24 hours. This includes lifting, bending, doing housework and gardening, or doing exercise such as jogging or bicycle riding. We will call you the day after the spinal tap to check on you.

We will check the levels of proteins on the sample we obtained and if they show protein build-up then you qualify for this study and you will be scheduled for the baseline visit. This may take few weeks.

Baseline Visit
Once eligible, you will be asked to come in for the baseline visit. You can complete this visit on one day or divide it into 2 visits. During this visit, we will measure your blood pressure and heart rate twice while you are seated and 1 and 3 minutes after standing. We will measure your weight and height. We will also perform tests to assess your thinking abilities, your mood, your balance and how fast you can walk. We may record

your voice for 5-10 minutes to assess certain patterns in your speech. This will be done during the memory tests or during a different time at one or more of your visits. We will also ask you to complete a few questionnaires regarding your physical and daily activities, levels of stress and health habits. Some of these will be mailed to you so you can review before your visit. A blood sample may also be drawn to measure the number of stem cells in the blood, the degree of inflammation and genetic profiles, if it was not performed during the screening visits. A spinal tap will also be performed if it was not performed during the screening visits. You may elect to have the spinal tap on a separate visit by itself.

You will also have an assessment of the arteries in your neck, also called carotid artery. We will ask you not to eat for at least 2 hours before this test. We will use a sound wave machine or an ultrasound to see if you have hardening of the arteries. We will first apply gel on your neck and then use a small camera that touches your skin to take pictures of your carotid artery. There is no radiation during the ultrasound assessment. We will also measure the degree of hardening of the arteries in your finger and arm. To do so we will apply a small blood pressure cuff on your arm and inflate it for 5 minutes. We will then release the pressure from the cuff. We will measure the degree of change in the arteries before and after the cuff inflation.

What is a brain MRI?

You will also have a brain scan (MRI) at the baseline visit and at the final visit. MRI of the head will provide us with detailed information about your brain. The MRI does not use x-rays or radiation. These scans will take about 50-70 minutes. Before you have the scan, you will be asked to remove all metal objects (like earrings or watches) from your body. Throughout the exam, there will be loud thumping noises coming from the wall of the scanner. Earplugs will be provided to help reduce the noise. You may feel a warming sensation in your body during the MRI. You must lie still on a padded table during the scan. We will be continuously monitoring your comfort level during the scan procedure. We may also record the amount of carbon dioxide that you breathe out of your nose. During the scanning procedure, we may place a mask on your face and ask you to breathe a mixture of air including small amounts (5-8%) of carbon dioxide for about 2 minutes.

PET scan

In a subset of participants, we will also be performing Positron Emission Tomography (PET) scan. The scan allows doctors to detect presence amyloid and tau build up inside the brain of a living person. he PET scan in this study uses very small amounts of radioactive imaging agents, called Pittsburgh compound B (PiB) and T807, to make a picture showing how much amyloid and tau has been built-up in your brain. It is possible that you will be asked to have one of the PET scans during the screening phase of the study (rather than the baseline visit) in order to see if you have protein build up.

During the PET scan a catheter (hollow plastic tube) will be placed in a vein in your arm and you will undergo the infusion of the imaging agent. You will then be positioned on the scanner bed while the scanner takes pictures for 30-45 minutes. During this time, you must hold your head as still as possible.

Retinal Scan and Blood Sample

This test is optional and will not affect your participation in this trial. If you agree and are eligible to participate in the retinal scan, we will take digital images of your retina with dilation using a device very similar to that used during a visit to an eye doctor. This procedure lasts approximately 45-60 minutes. We may also ask you to provide 2 teaspoons (10mL tube) of blood that will be used for research purposes. These samples and images may be shared with other researchers.

Follow-up visits

You will then be randomly prescribed either candesartan 8 mg once a day or placebo (inactive pill) once a day. You will then be seen every two weeks where the dose will be increased to 16 mg and 32 mg or matching placebo. Once maximal dose is achieved, you will be seen every three months (total of 4 visits) until the study ends. During the last visit, we will repeat your MRI, spinal tap and PET scan if you were selected to have a PET scan. Blood samples will be drawn during each of these visits.

During the follow-up visits, we may ask you questions regarding your social and functional history including your health habits, level of stress, and your ability to perform the activities of daily living. We may also ask you about your medical history, review the medications you are currently taking, measure your weight, height and blood pressure, and asses your balance, strength and walking speed.

How will my medicine be provided?

The medicine that you will take will be dispensed in a capsule format in a labelled bottle by the pharmacy and delivered to the principal investigator or study team member. The medication will either be provided to you at your visit or mailed to you. If you have questions about the medicine you may call the study clinical personnel, the principal investigator or the pharmacy. The number for the pharmacy is included on your medicine package. Candesartan is an FDA-approved medication for treating hypertension but not for cognitive disorders.

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.

Test results and incidental findings

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. All blood and CSF tests and vascular assessments are done for research purposes only.

You will also be getting brain scans for research purposes only. However, if the researchers have a question about something they see on the scan they will tell you and refer you to your primary care provider or another physician of your choosing for further clinical evaluation.

What are the possible risks and discomforts?

Cognitive testing assessment may be accompanied by anxiety, frustration and overall fatigue. The attachment and removal of a blood pressure cuff, cuffs for venous occlusion, and ultrasound probe on the neck may cause mild discomfort. Brain imaging requires you stay still and lie down for prolong time, which may cause boredom and minimal reversible back pain. Because of the closed space and noise, undergoing an MRI may be associated with anxiety or panic reactions. The potential side effects from CO2 inhalation may include a feeling of dizziness, faintness, or anxiety.

The more common side effects from candesartan include: dizziness (4%), back pain (3%), upper respiratory tract infection (6%), pharyngitis/sore throat (2%), and runny nose (2%).

The less common risks (occurring around 1%) are: fatigue, leg edema, chest pain, headache, bronchitis, coughing, sinusitis, nausea, abdominal pain, diarrhea, vomiting, and joint pain.

These adverse events have been reported in around 0.5% of participants: fever, vertigo, heartburn, rapid heartbeat/heart fluttering, kidney failure, increased potassium, muscle aches, swollen face, lip or tongue, rash, and shortness of breath. There may also be side effects from the study drug or procedures that are not known at this time.

If you experience any adverse, call your doctor and the study personnel immediately.

If you will be taking the study drug home, keep it out of the reach of children or anyone else who may not be able to read or understand the label. Do not let anyone else take the study drug besides you.

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.

The most common complication of a spinal tap is a headache (5-10%). We use a thin spinal needle that decreases the risk of headaches to less than 10%. Please contact the study personnel or investigators if it persists beyond 3 days. Infection and bleeding are rare complication of a lumbar puncture, occurring in less than 1%.

In very rare instances, a leak of CSF may occur. A leak means that your body did not heal the area where we obtained the CSF sample. If it persists this can be closed by a blood patch. A blood patch includes injecting a very small amount of your blood into that area where there is a leak. If the physician determines that a blood patch (applying a few drops of your blood on the site where the spinal tap was done) is necessary, you will not be billed for this procedure.

If you were selected to have a PET scan, you will be exposed to radiation from nuclear medicine. The estimated radiation dose that you will receive is within limits acceptable to the Emory University Radiation Safety Committee. We have not encountered systemic toxic effects attributable to single dose T807 or PiB. Both ligands are rapidly cleared from the plasma and their binding to their target is temporary. Toxicity or allergies to PiB or T807 remain a possibility and you will be monitored for such events during the scan and at follow-up. Infection, bleeding and transient discomfort may be encountered from the intravenous catheter introduced in your arm vein during this scan.

Principal Investigators shall immediately (within 24 hours of the event) report to the Radioactive Drug Research Committee all adverse effects associated with the use of the radioactive drug in the research study. All adverse reactions probably attributable to the use of the radioactive drug in the research study shall be immediately reported (within 24 hours of receiving the initial report) by the RDRC to the Food and Drug Administration, Center for Drug Evaluation and Research.

If you were selected to have retinal imaging performed, adverse reactions to dilation of the eyes may include discomfort, irritation, or other reactions similar to pupillary dilation experienced during a visit to the eye doctor. Increased sensitivity to bright lights is commonly experienced, and we will provide disposable sunglasses to counteract these effects. You will be monitored for adverse effects.

Will I benefit directly from the study?

This study is not designed to benefit you directly. Your thinking skills may or may not improve while you are in this study, and they may even get worse. This study is designed to learn more about the effect of candesartan on the protein buildup in the brain. The study results may be used to help others in the future.

Will I be compensated for my time and effort?

Compensation for your participation in these study visit will be in the form of gift cards. You will be compensated for your effort and time at the following schedule:

- Screen Visit: $25 + $100 (for lumbar puncture procedure)
- Baseline Visits: $100 (for visit + MRI) + $75 for each PET scan (optional)
- Titration Visits (2): $10
- 3 & 9 Month Follow Up Visits: $25
- 6 Month Follow Up Visit: $50 (cognitive testing, blood draw)
- 12 Month Follow Up Visits: $100 (for visit + MRI) + $75 for each PET scan (optional) + $100 (for lumbar puncture procedure)
- Return Visit for blood redraw: $20 and LP $100 (as needed)
- Retinal Imaging: $25
- Transportation: Up to $30 for gas reimbursement and up to $50 for taxi or shuttle service to the study site

You may be asked to fill out a tax form, including your Social Security or Taxpayer Identification Number, in order to be reimbursed, depending on the amount and method of payment. Some payment methods involve mail coming to your house, which may be seen by others in your household. You can decline payment if you are concerned about confidentiality, or you can talk to the study team to see if there are other payment options.

What are my other options?

If you decide not to enter this study, there is care available to you outside of this research study. [List the major standard care options and/or possibility of other studies; if the study compares two standard care treatments, state which one the subject would be most likely to get outside of the study, if applicable]. The study doctor will discuss these with you. You do not have to be in this study to be treated for your memory symptoms.

Taking part in this study, however, will make you unable to participate in other research studies. You should discuss this with the study personnel if you have concerns. You may wish to research other study options at websites like clinicaltrials.gov and ResearchMatch.org.

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.

Study records can be opened by court order. They also may be provided in response to a subpoena or a request for the production of documents.

Storing and Sharing your Information

Your samples, study data and health information will be stored and shared with other researchers. The samples and information will be available for any research question, such as research to understand what causes certain diseases (for example heart disease, cancer, or psychiatric disorders), development of new scientific methods, or the study of where different groups of people may have come from.

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.

Emory Healthcare may create study information about you that can help with your care. For example, the results of study tests or procedures. These study results will be put in your Emory Healthcare medical record. Anyone who has access to your medical records will be able to have access to all the study information placed there. 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.

Tests and procedures done at non-Emory facilities 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.

How is my Genetic Information Protected? What are the Risks?

The Genetic Information Nondiscrimination Act (GINA) is a federal law that generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance, and does not apply to employers with less than 15 employees.

In addition to GINA, the State of Georgia has laws that prohibit insurers from using genetic testing information for any non-treatment purpose. However, like GINA, this state law protection has exclusions: life insurance policies, disability income policies, accidental death or dismemberment policies, Medicare supplement policies, long-term care insurance policies, credit insurance policies, specified disease policies, hospital indemnity policies, blanket accident and sickness policies, franchise policies issued on an insurance policy

written as a part of workers' compensation equivalent coverage, or other similar limited accident and sickness policies.

Privilege

In the State of Georgia, your genetic information has special legal protections called "privilege," which means that the information cannot be used as evidence in a court. By signing this form and allowing us to use and disclose your genetic information for the purposes described in this consent, you waive any privilege with regard to that genetic information, meaning that the information loses this legal protection.

Genomic studies, including genome-wide association studies (GWAS), examine genetic differences in the entire human genome (the complete set of human genes) and the association between these genetic differences and health conditions.

In Case of Injury

If you get ill or injured from being in the study, Emory will help you get medical treatment. Emory and the sponsor have not, however, set aside any money to pay you or to pay for this medical treatment. The only exception is if it is proven that your injury or illness is directly caused by the negligence of an Emory or sponsor employee. "Negligence" is the failure to follow a standard duty of care.

If you become ill or injured from being in this study, your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurer does not pay, then you will have to pay these costs.

If you believe you have become ill or injured from this research, you should contact Dr. Ihab Hajjar at [redacted] You should also let any health care provider who treats you know that you are in a research study.

Costs

There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities.

Withdrawal from the Study

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

For your safety, however, you should consider the study doctor's advice about how to go off the study treatment. If you leave the study before the final planned study visit, the researchers may ask you to have some of the final steps done.

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.

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.

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 exams, procedures and tests you have before and during the study.
- 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 use and share your PHI to provide you with study related treatment and for payment for such treatment. 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, Institutional Review Boards (IRBs) and other study sites. If you leave the study, we may use your PHI to determine your health, vital status, eligibility or contact information. We will use and disclose your PHI for the administration and payment of any costs relating to subject injury from the study.

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. We will also comply with legal requests or orders that require us to disclose your PHI. These include subpoenas or court orders.

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 to authorize the use and disclosure of your PHI. If you do not sign this form, then you may not participate in the research study or receive research-related treatment. You may still receive non-research related treatment.

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 and give you study related treatment.
- Emory may use and disclose your PHI to get payment for study related treatment and to run normal business operations.
- 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 research team may use and disclose your PHI, including disclosure to insurance carriers to administer payment for subject injury.
- 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.
- Government agencies that regulate the research including: Office for Human Research Protections and the Food and Drug Administration.
- 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.

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 [redacted]:

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 study.

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.

<u>Contact Information</u>

[redacted]

- if you have any questions about this study or your part in it,

- if you feel you have had a research-related injury or a bad reaction to the study drug, or
- if you have questions, concerns or complaints about the research

Contact the Emory Institutional Review Board [redacted]

- 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.

TO BE FILLED OUT BY SUBJECT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in the study. 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

Signature of Subject (18 or older and able to consent) **Date** **Time**

Signature of Legally Authorized Representative with authority for research decisions **Date** **Time**

Authority of Legally Authorized Representative or Relationship to Subject

TO BE FILLED OUT BY STUDY TEAM ONLY

Name of Person Conducting Informed Consent Discussion

Signature of Person Conducting Informed Consent Discussion **Date** **Time**

STUDY PARTNER INFORMATION AND CONSENT

As the participant's study partner, you have the important tasks of providing important assistance to the enrolled participant to complete the study accurately.

These responsibilities include providing information about the participant's physical and thinking abilities and informing the study personnel about any significant changes in these abilities. You also agree to come with the study participant for his or her exams and evaluations. If you cannot come to the study center, then you agree to be available by phone to discuss with the study personnel the participant's physical and thinking abilities.

If for some reason you become unable to carry out these responsibilities, please tell the study coordinator immediately. You may be asked, if possible, to select a substitute who can take over your duties.

AGREEMENT:

I have read (or someone has read to me) all the preceding information which describes both the participant's involvement in the study and my involvement as the participant's study partner. I have been given a chance to ask questions. All my questions have been answered. By signing this form, I am agreeing to take part in this study.

_____ _____

Name of Study Partner (print) *Signature* *Date*

I have personally explained the research to the research participant and answered all questions. I believe that he/she understands the information described in this informed consent and freely consents to participate.

_____

Name of Investigator/Person Obtaining Informed Consent (print) Signature Date