Informed Consent Form

Health Evaluation in African Americans using RAS Therapy:

The HEART Project

IRB Approval Date: January 13, 2021

NCT Number: NCT02471833

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: Healthy Evaluation of African American using RAS Therapy

Principal Investigator: Dr. Whitney Wharton, PhD., Associate Professor
Emory School of Nursing Department of Academic Advancement; Emory School of Medicine Department of Neurology

Sponsor: Alzheimer's Association; National Institute of Health

Sites: Wesley Woods Health Center, Executive Park

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 are a member of the Alzheimer's disease Research Center (ADRC), your participation in that research will also not be affected if you decide not to participate in this study. If you decide not to participate, the health care provided to you by Emory University and its affiliates will not be affected in any way.

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.

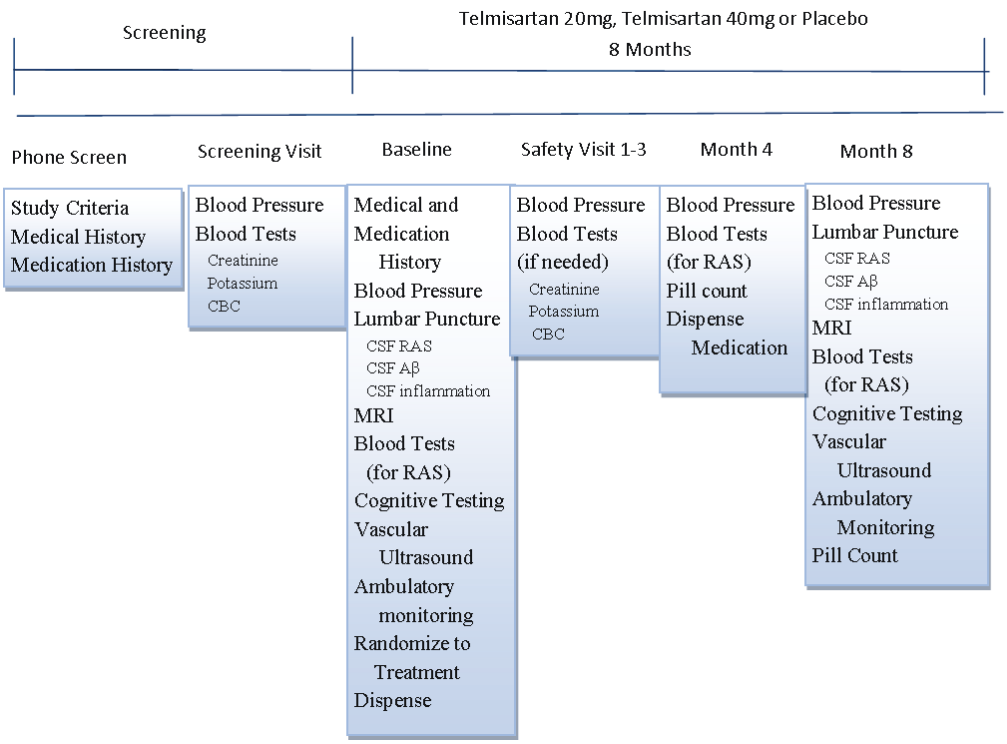
The purpose of this study: This trial is going to see if an FDA approved blood pressure medication may also have beneficial effects on Alzheimer's disease (AD) prevention in African Americans. Blood pressure medications known as angiotensin-receptor blockers have been associated with reduced risk of Alzheimer's in Caucasians because they act on the renin-angiotensin system (RAS), a key regulator of blood pressure in the body and the brain. The drugs appear to slow the progression of the disease by affecting flow of blood and the amount of plaque in the brain, but these benefits have not been tested in African Americans. This trial will evaluate if Telmisartan is able to influence the RAS in the brain and produce favorable effects on brain blood flow and enzymes that cause the brain plaques in Alzheimer's disease.

You have been invited to participate because you are 30 years or older and have a family history of Alzheimer's. We will test your blood pressure, blood, and ask questions about your health and thinking abilities at our first meeting to confirm that you are eligible to take part in the study.

About 66 individuals will take part in this research study at Emory University

Study Design: If you decide to take part in this study you will sign this informed consent form and your participation will last 8 months**.** Your participation in the study involves coming to the study sites at Emory University Executive Park (Buildings 6 and 12) and Wesley Woods CSI for interviews, brain scans, a vascular ultrasound (PWV), a collection of cerebral spinal fluid and blood tests. You will receive all blood pressure medications during your involvement in this study. The duration of this study is 8 months. You will be asked to visit the study site approximately 5-8 times during the months of your participation. The table below shows the outline

Figure 1



of the HEART PROJECT procedures by visits (screening, baseline, safety visits, month 4 and month 8). The procedures and timeline are described below.

Screening visit (approximately 2 hours): During this visit, we will sign the informed consent, explain the study details, ask you questions about your medical conditions and medications, check your blood pressure, take a blood sample (about 1 teaspoon), and questions about your health and thinking abilities. Please note that a large proportion of potential participants will not be eligible based on the results of these tests. If your systolic blood pressure reading (the upper number) must be equal or greater than 110 mmHg but less or equal to 170 mmHg (average of two bpm readings), if your systolic (upper number) is not within this range then, for your safety, you will not be enrolled in the study. We will also test your kidney function and potassium levels in your blood and your complete blood count (CBC). If these levels are not in a normal range, you will not be enrolled in the study.

If you do not qualify then **we will not proceed** with your study participation and you will not undergo any of the procedures in the reminder of this document.

We will call you with the results of the blood tests and let you know your eligibility to participate.

If you are eligible based on the results of your screening visit and agree to participate, we will enroll you in the study. At this time, we will give you a letter to inform your primary care doctor that you are interested in participating in a research study and that we will be placing you on the study blood pressure medication (or placebo). We will provide you with a supply of the study drug (Telmisartan 20 mg, Telmisartan 40 mg or placebo) and ask you to start the study medication starting at your Baseline visit, after you perform the baseline study procedures. This medication will be taken before bedtime. Any questions about the medication can be answered by the study physician or nurse.

As a required intervention and to achieve blood pressure control to below 140/90 mm Hg, other non-RAS acting medications (e.g. HCTZ, amlodipine, and metoprolol) may be commonly prescribed by your primary care doctor

Baseline Visit (3 and a half to 5 hours): This visit can happen all in one day or take place over two days, depending on your schedule. During this phase, blood pressure measurements, detailed neuropsychological assessments, physical exam, brain MRI, lumbar puncture and vascular ultrasound will be completed. Blood samples will also be collected for inflammatory and endothelial markers. This blood sample will also be used for APOE genetic testing. This testing can reveal information about your risk for Alzheimer's disease. You will not be informed of these results through this study. You will also be asked to wear a blood pressure monitor for 24 hours, which we will ask you to return the next day or at the second baseline visit, if everything is completed over two days. This procedure can be omitted, if you are unable to return the monitor. When you return the cuff or all mandatory procedures are completed, you will receive the first half of your gift card for participating ($75).

Once you have completed these tests, we will then randomly assign you (like flipping a coin) to receive Telmisartan 20 mg, Telmisartan 40mg or placebo. We will give you a 1 month supply of your assigned drug, a study physician or nurse will answer questions on you on how to take it, and ask you to come back in 2 weeks. The study will be double-blinded meaning that neither you

nor the principal investigator or study personnel will know which study drug you are taking. However, the study doctor will be aware of the study drug you are taking for safety reasons but will not disclose this information to you or the other members of the study team.

Safety visits (approximately an hour): These visits will last about 30-60 minutes. The first safety visit occurs about 2 weeks after the date of randomization (first visit where you received your study medication). We will measure your blood pressure in the seated position during these visits and address any adverse events or changes to your non-study medications. A blood sample may be drawn (half to 1 teaspoon) to check your potassium level and kidney function (if needed).

If your blood pressure is systolic (upper number) is lower than 90 mmHg then the study physician will advise you to immediately see your primary care physician. With your permission, we will also contact your physician. Blood pressure higher than 140/90 or lower than 90/60 after randomization will not exclude you from the study.

If your blood pressure and blood levels are all within normal limits, you will return for the Month 4 visit. If your limits are not in the normal range, you may be asked to return for additional safety visits or asked to visit your Primary Care Physician.

Month 4 (approximately 1 to 2 hours): You will be asked to bring your study medication bottles to this visit and the study team will perform a pill count on any remaining study medication for medications compliance purposes. We will then give you new medication bottles which will last you for the duration of the study. We will measure your blood pressure in the seated position and address any adverse events or changes to your non-study medications. We may also collect height and weight. A blood sample will be drawn for research purposes. Dispense of your next supply of study medications will be given or mailed to you.

Month 8 (approximately 3 to 4 hours): This visit is exactly like your baseline visit and is done in one day with the option to divide into 2 days. You will be asked to return your study medication pill bottles. During this phase, blood pressure measurements, detailed neuropsychological assessments, physical exam, brain MRI, lumbar puncture and ultrasound will be completed. Blood samples will also be collected for inflammatory and endothelial markers. You will also be asked to wear a blood pressure monitor for 24 hours, which we will ask you to return the next day. This procedure can be omitted, if you are unable to return the monitor. As with the Baseline visit, you will receive your remaining gift of $75.00 when you return the blood pressure monitor or all mandatory procedures are completed.

Study Procedures:

MRI Scan: The MRI scanner will be used to collect detailed pictures of your brain while you are lying still on the scanner bed. You are asked to fast (not eat) for 8 hours prior to this procedure. Two monitors will be comfortably secured to you to measure your pulse and respiration rates during the scan. During the scans it is essential for you to remain as still as possible to avoid any blurring of the images. Your head will be held in place by foam padding to help you keep still during the scan. The procedure takes approximately 1 hour. We will situate you as comfortably as possible and then run several scans that take 2-10 minutes each. In between scans, you will be able to communicate to the scan operator through an intercom. The MRI will be performed at the Wesley Woods Health Center. Before your scan, you will be asked a series of medical history questions to make sure you are safe to go into the scanner. This type of brain scan is not designed to detect problems of the brain. A radiologist will not be reading the scan. However, it is still possible that we will see something on your scan that is potentially abnormal, but may be nothing. If this happens, we will discuss it with you. This may cause you to seek further medical treatment and incur costs associated with that.

Risks of MRI: Some people should not participate in MRI studies. These include persons with shrapnel or certain metallic implants, such as prostheses, or aneurysm clips, or persons with electronic implants, such as cardiac pacemakers or implanted hearing devices. The magnetic field generated by the MRI machine can cause a displacement or malfunctioning of these devices. There are no other known risks to body tissues associated with the magnetic field strength used in this study. Some participants report some anxiety or claustrophobia in the MRI scanner since the head must be placed fully inside the scanner tube. If anxiety or claustrophobia occurs, please let us know and we will stop the scan and bring you out of the scanner. In addition, fatigue and physical discomfort are possible. The MRI scanner makes a great deal of noise when taking images. To minimize the level of noise, you will be fitted with disposable earplugs or headphones to wear during the procedure. These may be a bit uncomfortable to wear, and will not eliminate all sound, so that communication with you is still possible.

Cognitive Testing: At baseline and 8 month study visits, you will undergo about 60 minutes of cognitive testing. This will include computerized and paper and pencil tests that will look at areas of cognitive functioning such as verbal ability, spatial ability and memory.

Questionnaires: You will be asked to complete medical and health related surveys. The surveys ask questions about your sleep habits and problems; about your medical history and medications; about your exercise habits; about your mood and mood changes; and about your diet and stress levels. The surveys are the same each time and take about an hour total to complete. You may complete these questionnaires prior to your visit via email.

During the course of this eight month study, you may be asked to complete additional questionnaires, some of which may be completed online. These questionnaires include but are not limited to – mood, stress, the quality of life of your family member with Alzheimer's disease, nutrition, and exercise.

Risks of Cognitive Testing & Questionnaires: During tasks that involve memory, you may become bored, fatigued, or frustrated by their difficulty. There are no physical risks to these tests. Some of the questions you will be asked on the questionnaire are personal and may make you feel embarrassed. You may skip any questions you do not feel comfortable answering, but it is important for you to give your best effort.

Blood Sample: About five to six tablespoons of your blood will be drawn from a vein in your arm. This should only take about 5 minutes.

Risk of Blood Draw: We will collect a blood sample at all visits. Blood draws can cause mild pain in the arm and may cause bruising, infection, and occasional fainting.

Neurologic Exam: A physician or nurse practitioner will do a neurological and physical exam prior to the lumbar puncture.

Lumbar Puncture: A lumbar puncture is a procedure using a needle to remove spinal fluid from the lower back. For this fasting 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 then be numbed with a drug called Lidocaine. Lidocaine will help reduce any pain that may be caused by this procedure. A thin needle (typically 1/48 of an inch wide, and 3.5 to 4 inches long) will be placed into the space that contains the spinal fluid, which is below where the spinal cord ends. One and a half tablespoons of spinal fluid will be removed and the needle withdrawn. If you have your lumbar puncture for this study done at the same time as a lumbar puncture for another study, then we might draw up to 25 mLs (about 5 teaspoons of fluid) from your back. During either of the two study visit lumbar puncture procedures, if no spinal fluid is obtained on the first attempt, a second attempt will be made after numbing the area with Lidocaine. If the sample of spinal fluid is not drawn, you will be offered the opportunity to attempt to repeat the procedure or you will not undergo another lumbar puncture and remain in the study. The lumbar puncture procedure will take approximately 30 minutes. After the lumbar puncture is completed, you will lie on your back for about 20 minutes.

Risks of Lumbar Puncture (LP): Approximately 22-25 milliliters (1 ½ Tbs) of spinal fluid may be taken during each LP and your body will make up for the loss. During the procedure, you may have temporary pain and discomfort in your back. The most common complication of spinal fluid collection is a headache. When done in most clinical settings, headache occurs in about 10 out of every 100 people who have the procedure. On the other hand, the number of people who get headaches is less than 2 out of every 100 people when a special needle is used. This special needle is used for spinal fluid collection in every lumbar puncture in this study.

Drinking a lot of water before the spinal fluid collection may also help prevent headaches, and drinks with caffeine may help treat headaches from spinal fluid collections. If this headache persists it may require additional treatment with over the counter medications. This often relieves the headache immediately. Rarely a blood patch (injection of some of your blood into the lumbar puncture site to patch the spinal fluid leak) may be required. We will call you the day after your spinal fluid collection to see if you have any side effects.

During the spinal fluid collection, about 13% of people feel brief sensitivity if the needle touches a nerve. Damage to the nerves that come off the spinal cord can rarely occur that may result in leg tingling. In 1 out of every 150,000 people, bleeding from a broken blood vessel can cause a pocket of blood that may affect the spinal cord or brain. If the procedure is performed at the improper

level, the needle may injure the spinal cord. A nurse practitioner or doctor does a physical exam and will speak with you before the spinal fluid collection to make sure you have no neurological conditions that would make spinal fluid collection unsafe.

Infection is a rare, but possible side effect. To minimize this risk, sterile gloves and equipment are used for the procedure and betadine is used to clean the skin at the lumbar puncture site.

Lidocaine: Lidocaine is the drug used to numb the lower back before the collection of spinal fluid. There are rare cases of allergic reactions to lidocaine, such as redness and swelling of the skin. If you have had a previous reaction to lidocaine, please inform study personnel right away.

Pulse Wave Velocity (Vascular Ultrasound): This procedure is non- invasive and will be used to measure arterial stiffness. The procedure will require you to lie still on your back while a trained study team member administers the testing. This procedure will take approximately 30 minutes to an hour and is performed on baseline and month 8 study visits.

Risks of Blood Vessel Function Tests: The brachial artery ultrasound is safe and only mildly uncomfortable due to tightness in the arm and/or leg when the cuff is inflated. We will use ultrasound to painlessly bounce sound beams off of your carotid artery to determine how much blood is flowing out of it. We will place a pencil-like sensor gently against the inside your neck and record a blood pressure signal from your pulse. This measure is also painless and is non-invasive.

Ambulatory Blood Pressure Monitoring: The ambulatory blood pressure monitoring device is non-invasive and only mildly uncomfortable due to tightness in the arm when the cuff is inflated. The monitor consists of a blood pressure cuff, like you have probably seen in the doctor's office, which is connected to a small lightweight battery pack that can be worn on a belt or placed in your pocket. You will wear the cuff for 24 hours. The blood pressure cuff will inflate and take your blood pressure automatically 3 times per hour while you are awake and 1 time per hour while you are asleep. You blood pressure information will automatically be stored in the monitor and this information will be used by the Principal Investigator and The HEART project team. You can wear the blood pressure monitor home with you and do all of your normal activities, except that you should take it off to shower, bathe, or swim. The cuff inflates 3 times per hour while you are awake, and once an hour while you are asleep. You will be asked to fill out a diary of your activities during these 24 hours. The cuff is expected to be returned back to the study team at the second scheduled baseline visit or Safety Visit that will be scheduled within two weeks.

Risks of Blood Pressure Cuff: The blood pressure monitoring device is non-invasive and the most common complaint is potential discomfort due to the blood pressure cuff inflating. If this occurs, you simply can take off the cuff.

Distribution of Medication: The medicine that you will take will be dispensed by the Emory pharmacy and delivered to the principal investigator or study team member. The principal investigator or health care providers on the research team will provide the medicine to you. If you have questions about the medicine, you should ask the principal investigator or study physician. You may also call the pharmacy if you have questions about the medicine. The number for the pharmacy is included on your medicine package.

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. We will use and disclose your PHI for the conduct and oversight of the research study. We will 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 or contact information.

Genetic Information: The Genetic Information Nondiscrimination Act (GINA) is a federal law that protects against genetic discrimination. This law makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on you genetic information. This law does not protect you from being discriminated in life insurance, long-term care insurance, or from employers with less than 100 workers.

Risks and Discomfort: There may be side effects from the study drug or procedures that are not known at this time.
The medications that will be given during the course of the study are Telmisartan and are approved by the Federal Drug Administration (FDA) and are commonly used by doctors to treat high blood pressure.

The possibility of side effects or an allergic reaction related to these medications is no different than if your doctor prescribed them. You will be carefully monitored throughout the study for any side effects related to these medications. The potential side effects are listed below. Please tell the study doctor or personnel if any of these symptoms are severe or do not go away.

Telmisartan: headache, dizziness, asthenia, coughing, nausea, fatigue, weakness, edema, face edema, lower limb edema, angioneurotic edema, urticaria, hypersensitivity, sweating increased, erythema, chest pain, atrial fibrillation, congestive heart failure, myocardial infarction, blood pressure increased, hypertension aggravated, hypotension (including postural hypotension), hyperkalemia, syncope, dyspepsia, diarrhea, pain, urinary tract infection, erectile dysfunction, back pain, abdominal pain, muscle cramps (including leg cramps), myalgia, bradycardia, eosinophilia, thrombocytopenia, uric acid increased, abnormal hepatic function/liver disorder, renal impairment including acute renal failure, anemia, and increased CPK, anaphylactic reaction, tendon pain (including tendonitis, tenosynovitis), drug eruption (e.g. toxic skin eruption mostly reported as toxicoderma, rash, and urticaria), and angioedema (with fatal outcome)**.**

Because each person reacts differently to medications, you may experience other side effects that are not listed above. Please tell the study doctors if you experience any discomfort or unusual symptoms after starting the medications provided by this study.

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.

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.

Benefits: This study is not designed to benefit you directly. You may gain knowledge about your blood pressure, and thinking abilities. The study results will be used to help others in the future.

Compensation: Participants will be compensated a total of $150 for their participation, $75 will be given at the conclusion of the baseline visit and the remaining $75 after the conclusion of the Month 8 visit. Compensation will be given in the form of gift cards**.**

Other options: This is not a treatment study. If you decide not to enter this study, there is care available to you outside of this research. You can continue with your current care for your blood pressure. If you have high blood pressure and you are not receiving blood pressure medications, your primary doctor may use other blood pressure medications to lower your blood pressure. The study team will discuss this with you.

Protection of private information collected in this study: Emory will keep any research records that it creates private to the extent that this is required to do so by law. 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.

Any data or samples leaving Emory will be coded. Researchers at Emory might need to know your identity in order to match your information and samples with the information we collect from you in other studies that you participate in.

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.

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.

The results of some study tests and procedures will be used only for research purposes and will *not* be placed in your medical record. For this study, those items include: Ambulatory blood pressure readings and study visit blood pressure readings, cognitive testing results, ultrasound results, MRI imaging, research blood results, and CSF results.

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, though we will provide a letter to the physician who is treating your high blood pressure so that she/he is aware of the study.

In Case of Injury: If you get ill or injured from being in the study, Emory will help you to 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 the study staff at telephone number at [redacted]. You should also let any health care provider who treats you know that you are in a research study.

Costs: The study sponsor will pay for certain items or services that you may receive if you take part in this study.

You will have to pay for the items or services for which the study sponsor does not pay. The sponsor will not pay for your regular medical care. If you have insurance, Emory will submit claims to your insurance for items and services that the sponsor does not cover. Emory will send in only those claims for items and services that it reasonably believes your insurance will pay and that the sponsor has not paid.

The actual amount that you have to pay depends on whether or not you have health insurance and whether or not that insurance will pay for any research study costs. Generally, insurance companies will not pay for items and services that are required just for a research study. Some insurance companies will not pay for regular medical treatment or treatment for complications if you are in a

study. How much you will have to pay for any co-payments, deductibles or co-insurance depends on your plan. Emory and the sponsor will not pay for these costs.

It is a good idea to contact your insurance provider and tell them you want to be in this research study. Ask them what they will pay for and what they will not pay for. You can also ask the study team for help in figuring out what you will have to pay.

Withdrawal from the Study: You have the right to leave a 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.

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 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 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 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. 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 Alzheimer's Association 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.
- Public health agencies.
- Research monitors and reviewer.
- Accreditation agencies.
- The Data Safety and Monitoring Board for this study.
- Government agencies: U.S. Food and Drug Administration (FDA) and Office of Human Research Protections.

As part of this study, we will collect information about your health and your individual genes.
This information will be sent to a National Institutes of Health (NIH)-designated data repository that includes all kinds of genomic data from studies funded by the NIH.

The aim of collecting this information is to look for genetic connections that:

- **may increase the likelihood of getting a certain disease (such as asthma, cancer, diabetes, heart disease or mental illness) or a condition (such as high blood pressure or obesity)**
- **may affect the progress of a certain disease or condition**
- **may affect treatments (medicines, etc.) that work for certain diseases in some people, but not in others.**

We will remove direct identifiers (such as your name) and instead code your information before sending it to the repository. NIH will never get this code or the identifiers we have removed.
The repository is a controlled-access repository. Controlled-access data is only available to researchers and companies who apply to the NIH. The NIH will review data requests for scientific merit and for methods to protect data and methods to ensure data will be used for the approved purpose. We will not know what types of health-related research will be done with the data that are sent to the repository.

Expiration of Your Authorization
There is no expiration of your authorization

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 the study PI at:

Whitney Wharton, PhD
Associate Professor
Emory University
Nell Hodgson School of Nursing
[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.

Contact Information

Contact the study PI at [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 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

Please print your name and sign below if you agree to be in this 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 consent to keep.

_____
Name of Subject

_____ _____
Signature of Subject Date Time

_____
Name of Person Conducting Informed Consent Discussion

_____ _____
Signature of Person Conducting Informed Consent Discussion Date Time