

Candesartan vs Lisinopril effects on the Brain and  
Endothelial function in Executive MCI (CALIBREX)

Informed Consent Form approved on 10/12/2017

NCT01984164

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**Emory University**  
**Consent to be a Research Subject And HIPAA Authorization**

**Title:** Candesartan vs Lisinopril effects on the Brain and Endothelial function in Executive MCI (CALIBREX)

**Principal Investigator:** Ihab Hajjar, M.D.

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Section of Geriatrics

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**Sponsor:** National Institute of Health

**Investigator-Sponsor:**

**Study-Supporter:**

**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 to consent (agree) to be in the study or not to be in 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 is 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**

### **WHY IS THIS STUDY BEING DONE?**

High blood pressure can affect a person's thinking abilities. The purpose of this study is to compare the effect of two high blood pressure drugs, candesartan and lisinopril, on thinking abilities and brain activities. Both drugs are approved by the U.S. Food and Drug Administration (FDA) for treatment of high blood pressure. However, in this study they are considered experimental because they are being used to compare how the drugs affect memory and thinking abilities. If you agree you will be randomized, that is selected by a 50% chance, to take either candesartan or lisinopril for your blood pressure.

You have been invited to participate because you are 55 years or older and have high blood pressure. Participants must also have early/mild limitations in their thinking abilities. We will test your thinking ability at our first meeting to confirm that you are eligible to take part in the study.

About 160 individuals will take part in this research study at Emory University.

### **Procedures**

If you decide to take part in this study you will sign this informed consent form and your participation will last 1 year.

Your participation in the study involves coming to the study center at Emory University for interviews, brain scans, an ultrasound, and blood tests. You will receive all blood pressure medications during your involvement in this study and may have a physical examination during the study. The duration of this study is 1 year. You will be asked to visit the study site at least 5 times during that year. The following describes what happens at each visit:

#### **Screening visit: (40-60 minutes)**

During this visit, we will:

- Explain the study details
- Ask you questions about your medical problems and medications
- Check your blood pressure

- Test your thinking abilities. Please note that a large proportion of potential participants will not be eligible based on the results of these tests.

If you qualify and you agree to participate, we will enroll you in this study. You will be asked to identify an individual who is willing to act as a study partner and who is familiar with your daily activities, if needed. We will also draw a blood sample (half to 1 teaspoon).

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 remainder of this document.

**If you are taking blood pressure medications**, you will need to stop these medications before you start one of the two study medications used in this study (candesartan or lisinopril). We will take special steps to ensure your safety during the process of stopping your blood pressure medication:

1. If you agree, we will inform your primary care doctor that you are interested in participating in a research study and that your blood pressure medications will be stopped gradually.
2. We will give you an automatic blood pressure machine and a diary to take home with you. We will teach you how to use the blood pressure machine and ask you to measure and record your blood pressure twice a day (morning and before sleep).
- 3- You will also be contacted by the study staff at least once or twice a week (more if needed) to review your blood pressure recordings and your progress on decreasing your medications.
4. You will receive written instructions on how to lower your current blood pressure medications and eventually stop them. The instructions will give the dose of each medication that you will be taking each day until you completely stop all blood pressure treatments.
5. If your reading of the upper number is higher than 180 or the lower number is 110 or higher, we will ask you to repeat the blood pressure check within an hour. If the second reading is still above 180/110 or you have any unexpected discomfort, dizziness, or headaches we ask you to call us immediately at the number provided on the instruction sheet. The study physician will instruct you on what to do next: which may include altering the way your blood pressure medication is being reduced, take an extra dose of your blood pressure medication, or resume your usual doses of all your blood pressure medications immediately (the doses you were on before you started the study). You will continue measuring your blood pressure as instructed. The study personnel will then contact you daily to obtain the blood pressure readings. This will continue until your blood pressure is back to the level before you started the medication reduction or you have seen/contacted your primary care physician. For your safety, you will not be enrolled in the study if you could not stop your blood pressure medication.

6. We will see you at the study site after you have stopped your current medications. We will provide you with a supply of the study drug (either candesartan or lisinopril) and ask you to start the study medication the same day, after you perform the baseline study procedures.

**If you are not taking any blood pressure medications before the study**, then we will schedule the baseline visit without stopping any medication.

**Baseline Visit (3 and a half to 4 hours):**

You can complete this visit on one day or divide it into 2 parts. 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. Some of these will be mailed to you so you can complete them before your visit. A blood sample (1-and-a-half to 2-and-a-half Tablespoons) will also be drawn to measure the number of specialized cells in the blood that can line up your arteries, the degree of inflammation, and the APOE gene that is involved in making a protein called apolipoprotein E. A urine test will also be obtained to check for proteins in the urine. The blood and urine tests will be completed either at Emory University or an external laboratory. Your samples may be stored temporarily until shipped to the external laboratory at Emory University storage sites.

You will have an MRI of your head that will provide us with detailed information about the health of your brain. The MRI does not use x-rays or radiation. We would like your permission to share your information (after removing your name) with other research investigators and to contact you in the future if we need additional information. These choices are optional. You can still take part in this study even if you say no to these options. You will initial at the end of this form with your choice.

The MRI scans will be obtained at the Emory Center for System Imaging. These scans will take about 50-60 minutes. Before you have the scan, you may be asked to change into a gown and 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 monitoring your blood pressure, heart rate, and comfort level during the scan procedure. We will 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 (either as 2-minute continuously or as 1- minute intervals). Then, we may ask you to breathe faster than normal for 2 minutes. The digital pictures of your brain will give us information about your brain and the blood circulating into the various brain areas.

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. These tests will be completed at Emory University Hospital. Parking will be provided if needed.

Once you have completed these tests, we will then randomly assign (like flipping a coin) you to receive candesartan or lisinopril. There is about 50% chance of being assigned to either group. We will give you a month supply of your assigned drug (candesartan or lisinopril), instruct you on how to take it, and ask you to come back in 2 weeks. The procedures are similar for each of the assigned groups. The study will be double-blinded meaning that neither you nor the study doctor or personnel will know which study drug you are taking. For all study related testing, the test results will not be disclosed to you unless deemed necessary by the study Physician

**Medication adjustment visits:** These visits will last about 20-30minutes. The first one occurs 2 weeks after the baseline visit. We will measure your blood pressure twice in the seated position during each of these visits and at 1 and 3 minutes after standing. If your blood pressure is less than 140/90, then you will continue on the same dose, a blood sample will be drawn (half to 1 teaspoon) to check your potassium level and kidney function, and you will be scheduled for a follow-up visit in 3 months. We check potassium and kidney function to monitor for any changes as pressure medications may affect both.

If your blood pressure is 140/90 or greater, then we will increase the dose of your medication and request that you come back for another visit in 2 weeks. If your blood pressure is still 140/90 or greater, then we will increase the dose of your medication further. A blood sample will be drawn (half to 1 teaspoon) to check your potassium level and kidney function during this visit. Afterwards, we will see you every 2 weeks until your blood pressure is below 140/90. If additional medications are needed then hydrochlorothiazide, amlodipine or metoprolol will be added in progressive doses.

**Follow-up visits:** You will also be seen at 3, 6 and 12 months. We will measure your weight and blood pressure at each visit. We will also repeat your tests of the thinking abilities at 6 and 12 months. Your brain scan, neck ultrasound, walking speed, balance, and ability to perform daily activities will be measured again at 12 months. We will also obtain urine samples and draw blood samples at the 6 and 12 months visits: (1-and-a-half to 2-and-a-half Tablespoons). During this phase, we will also call you monthly to ask you if you have missed any doses of your blood pressure medications or if you have had any problem related to taking your blood pressure medication.

Once you complete the study, we will inform you and your primary care doctor of what medication you were receiving (un-blinding). You will have the option to continue on the same regimen that you were receiving in the study or go back to your previous medication regimen. We recommend that you discuss your options with your primary care doctor. You will need to make arrangements with your primary care doctor to discuss these options. We will supply you with one extra month of the medication regimen so that you have time to make arrangements with your primary care doctor.

### **Risks and Discomforts**

**Risks from stopping blood pressure medications:** During the medication switching phase there is a risk of severe elevation of blood pressure, dizziness, loss of balance or coordination, severe headache with no known cause, or difficulty speaking. These can be signs of a Stroke. Please Call 911 if you have sudden trouble walking, cannot speak, cannot move one arm, or you see drooping in your face. We ask that you share this information with your spouse, other members of your household, or someone you are in frequent contact with.

**Risks from the study medications:** The medications that will be given during the course of the study, lisinopril, candesartan, amlodipine, hydrochlorothiazide, and metoprolol are approved by the Federal Drug Administration (FDA) and are commonly used by doctors to treat high blood pressure. If you have a side effect or have developed a new medical problem that prevents you from taking the study medication you will be asked to resume your previous blood pressure medications. You will also be referred back to your primary care doctor for further blood pressure treatment. You will continue in the study and will be asked to come back for your scheduled visits.

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.

**Lisinopril:** Lisinopril may cause: cough, dizziness, headache, excessive tiredness, nausea, diarrhea, weakness, skin rash. The following symptoms are uncommon, but if you experience any of them, call your doctor and the study personnel immediately: swelling of the face, throat, tongue, lips, eyes, hands, feet, ankles, or lower legs, hoarseness, difficulty breathing or swallowing, yellowing of the skin or eyes, or fainting.

**Candesartan:** Candesartan may cause headache, dizziness, back pain, sore throat. The following symptoms are uncommon, but if you experience any of them, call your doctor and the study personnel immediately: swelling of the face, throat, tongue, lips, eyes, hands, feet, ankles, or lower legs, hoarseness, difficulty breathing or swallowing, or fainting.

You will be receiving the following additional medications if your blood pressure is not below 140/90 after taking candesartan or lisinopril. Their potential side effects are listed below:

**Amlodipine:** Amlodipine may cause swelling of the hands, feet, ankles, or lower legs, headache, upset stomach, stomach pain, dizziness or lightheadedness, drowsiness, excessive tiredness, flushing (feeling of warmth). The following symptoms are uncommon, but if you experience any of them, call your doctor and the study personnel immediately: more frequent or more severe chest pain, rapid, pounding, or irregular heartbeat, or fainting.

If you are currently taking a cholesterol lowering drug called SIMVASTATIN (Also called ZOCOR) and your dose is greater than 20 mg, then you cannot take Amlodipine due to the risk of causing muscle damage when used with more than 20 mg of Simvastatin. You will be able to take hydrochlorothiazide or metoprolol if your blood pressure is above 140/90.

**Hydrochlorothiazide:** Hydrochlorothiazide may cause frequent urination, which might go away after you take hydrochlorothiazide for a few weeks. Tell the study doctor if it does not. Other potential side effects include: muscle weakness, dizziness, cramps, stomach pain, nausea, vomiting, diarrhea, loss of appetite, headache, and hair loss. The following symptoms are uncommon, but if you experience any of them, call your doctor and the study personnel immediately: sore throat with fever, unusual bleeding or bruising, severe skin rash with peeling skin, or difficulty breathing or swallowing. Hydrochlorothiazide may also lower your potassium level. We will be monitoring potassium level during your participation in the study. If it becomes very low, we may ask you to take a potassium supplement.

**Metoprolol:** Metoprolol may cause dizziness or lightheadedness, tiredness, depression, nausea, dry mouth, stomach pain, vomiting, gas or bloating, heartburn, constipation, rash or itching, cold hands and feet, or runny nose. The following symptoms are uncommon, but if you experience any of them, call your doctor and the study personnel immediately: shortness of breath, wheezing, swelling of the hands, feet, ankles, or lower legs, unusual weight gain, fainting, rapid, pounding, or irregular heartbeat, or slow heart rate.

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.

We will also check if the study medications would interact with your other medications. The following list of medications cannot be used with one or more of the medications provided by this study. Please let us know if you are currently receiving these medications or if you get started on them while you are enrolled in this study: Simvastatin (also called Zocor) at doses greater than 20, reserpine (serpalan), clonidine (catapres) or lithium.

### **Risks from study procedures:**

There may be minor discomfort from the needle stick when a blood sample is taken during screening and follow-up visits and a small chance of a bruise in the area of the needle stick. In rare instances a person may experience dizziness and may faint during a needle stick.

You may experience anxiety, frustration and overall fatigue from the thinking tests. You can choose to skip or stop answering any questions that make you uncomfortable. There is possible minor discomfort of the ultrasound device placed against your skin. The inflation of the blood pressure cuff on your arm may make you feel like your arm went to sleep. This goes away after we deflate the cuff

Brain imaging requires you to stay still and lie down for 50-60 minutes which may cause slight back pain. You may feel claustrophobic (fear of enclosed spaces) or anxious since you will be enclosed in a closed space. If you experience claustrophobia while in the machine the scan will be stopped at your request. Some people may be uncomfortable due to the loud noise that occurs during the scan. You will be given earplugs to protect your ears. During the scan, a small percentage of people may experience muscle twitches, tingling sensations, or headaches, but these sensations are not harmful. If you experience such sensations, immediately report them to the operator and adjustments will be made to prevent such sensations.

There is a chance that you may feel dizzy or lightheaded when breathing through the mask or breathing carbon dioxide. If you feel dizzy or lightheaded, we will stop the flow of CO<sub>2</sub> and the mask will be removed.

Women of childbearing potential will not be included in the study.

When you take 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.

### **New Information**

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.

### **Benefits**

This study is not designed to benefit you directly. However, the potential benefits may include improvement in your blood pressure to below the recommended target of 140/90. You may gain knowledge about your blood pressure, brain blood flow, and thinking abilities. Your participation will also help us understand how blood pressure can affect the brain and ways to prevent its effect. The study results may be used to help others in the future.

### **Compensation**

Screening Visit Compensation: If you complete the first part of the screening visit (consent and thinking test) you will receive a \$10 gift card. If you complete both parts of the screening visit (consent, thinking test, physical exam, and blood sample) you will receive a \$25 gift card.

Study visit compensation: At the Baseline visit you will receive a \$75 gift card, at the 3 and 6 month follow up visits you will receive a \$25 gift card, and at the 12 month follow up visit you will receive a \$75 gift card. No compensation will be given during the blood pressure medication adjustment visits.

Transportation Reimbursement: If you need transportation to the study sites, we will reimburse you up to \$50 each way depending on the miles traveled (Maximum of \$100 per visit). This payment will also be given in the form of gift cards. A parking validation ticket (\$6 value) will be given to you if you drive and park at the Lowergate parking deck for the ACTSI portion of the study.

Because the payments for this study total to more than \$300 for the year, you will be asked to fill out a tax form, including your Social Security or Taxpayer Identification Number, in order to be reimbursed.

### **Other Treatment Outside this 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 similar or other blood pressure medications to lower your blood pressure. The study doctor will discuss these with you. You do not have to be in this study to be treated for your high blood pressure

### **Confidentiality**

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.

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.

Certain offices and people other than the researchers may look at your medical charts and study records. Government agencies and Emory employees overseeing proper study conduct may look at your study records. These include the Food and Drug Administration, the Office for Human Research Protections, Emory offices that are part of the Human Research Protection Program, and those that are involved in administration and billing. Study sponsors and people or companies they use to carry out the study may also look at your study records. A study number rather than your name will be used on study records wherever possible. Your name and other facts that might point to you will not appear when we present this study or publish its results.

### **Medical Record**

If you are or have been an Emory Healthcare patient, you have an Emory Healthcare medical record. If you are not and 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 your Emory Healthcare medical record.

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.

Emory does not control results from tests and procedures done at other places, so these results will not be placed in your Emory Healthcare medical record. They will likely not be available to Emory Healthcare to help take care of you. Emory does not have control over any other medical records that you may have with other healthcare providers. Emory will not send any test or procedure results from the study to these providers. If you decide to be in this study, it is up to you to let your health providers know.

The researchers will not be looking at the results of these tests and procedures to make decisions about your personal health or treatment.

### **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 and/or disclose (share) for the 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 disclose 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. 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 elder 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 authorize the use and disclosure of your PHI for the study, then you may not participate in the research study or receive research-related treatment. You may still receive non-research related treatment.

**People that will Use and/or 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 National Institute of Health 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 research team and the Sponsor 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 involved in study administration and billing. These include the Emory IRB, Western IRB, and other IRBs or privacy boards involved in this study; 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; Food and Drug Administration; Veterans Administration].
  - Public health agencies.
  - Research monitors and reviewers.
  - Accreditation agencies.

**Expiration of Your Authorization**

This authorization will not expire because it is a research study.

## **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 write to: Ihab Hajjar, MD.

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 are correct. If you revoke your authorization you will not be able to stay in the study.

## **Other Items You Should Know**

Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers or 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 and/or for other purposes besides this study.

## **In Case of Injury**

*If you get ill or injured from being in the study, Emory would 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 proved 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 trial, 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 telephone number 404-686-5500 ID number (extension) 71988. 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 the tests that were described above as part of the study conduct. The study sponsor will also pay for certain items and 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.

If you do not have insurance, Emory will review your case as part of its program for low-income patient care. The standard policies of that program will apply. The program will figure out if you have to pay any costs for taking part in the study and what those costs will be.

## **Withdrawal from the Study**

Your participation in this study is voluntary. Your decision whether or not to take part will not affect your current or future care at this institution. You are not giving up any legal claims or rights. If you do decide to take part in this study, you are free to change your mind and stop being in the study at any time.

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 if:

- They believe it is in your best interest;
- You were to object to any future changes that may be made in the study plan;
- If you fail to comply with the procedures of the study
- Or for any other reason.

### **Contact Information**

- Contact the study Doctor, Ihab Hajjar, at **404-7286959** or email [ihajjar@emory.edu](mailto:ihajjar@emory.edu). In case you need to reach him immediately you can *page him at telephone number 404-6865500 extension 71988*:
  - 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](mailto: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>.



## STUDY PARTNER INFORMATION & CONSENT

### 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.

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|--------------------------------------|------------------|-------------|
| <i>Name of Study Partner (print)</i> | <i>Signature</i> | <i>Date</i> |
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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.

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|---|-----------|------|
| Name of Investigator/Person<br>Obtaining Informed Consent (print) | Signature | Date |
|---|-----------|------|