You Are Being Asked to Be in a Research Study

Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study, you will be one of 3,000 people who are being studied at Emory.

Why is this study being done?
This study is being done to answer the question: how can we detect diseases of brain aging (such as Alzheimer's disease) as early as possible? You are being asked to be in this research study because your participation might help us identify markers of brain aging relevant to this question.

Do you have to be in the study?
It is your decision to be part of this research study. You do not have to be in it. Before you make your decision, you should take time to learn about the study.

What do I have to do if I choose to participate in this study?
If you are eligible and want to be part of the study, you may participate for as long as you are willing and able to do so (there is no set end date for this study). Every two years, the researchers will ask you to participate in the following at a study visit:

1) Questionnaires and health surveys
2) Cognitive assessments
3) Eye tracking evaluation
4) Vital signs
5) Blood draw
6) Lumbar puncture
7) Cardiovascular assessments
8) Magnetic Resonance Imaging (MRI)

You may also be asked to complete remote data collection by phone, email, or video conference using a secure Emory-approved platform (e.g., Zoom). Additionally, you may be asked to be an advocate for the study by participating in video recordings and/or providing testimonials.

All of these procedures will be paid for by the study.

How is this study going to help you?
If you are in the study, you will be helping the researchers answer the study question. This study is not designed to benefit you directly.

What are the risks or discomforts I should know about before making a decision?
The study will take time. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious – for this study, these include various side effects of some study procedures, loss of privacy, and breach of confidentiality. A full list of expected risks, their frequency and severity are in the "What are the possible risks and discomforts?" section of this document.

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

Costs
You will not have to pay for any of the study procedures.

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

Emory University
Consent to be a Research Subject / HIPAA Authorization

Title: **Emory Healthy Brain Study**

Principal Investigator: James J. Lah, M.D., Ph.D.

Performance Sites: Executive Park 6 and Executive Park 12 (Brain Health Center)

Sponsor Name(s): Emory University; National Institute on Aging

Introduction

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

Before making your decision:

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

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

What is the purpose of this study?

The purpose of the study is to discover markers of brain aging that will lead to early detection and treatment of specific brain diseases, such as Alzheimer's disease. We hope that early detection will lead to the discovery of effective treatments for those diagnosed with Alzheimer's disease and other brain disorders. Up to 3,000 people will participate in this research.

What will I be asked to do?

A study visit will include several procedures. You will be asked to provide biological samples and complete other assessments. These samples and assessments will be collected every two years. We will also ask to review information from your Emory medical record. You may be asked to release non-Emory medical records to the researchers.

Taking part in this study may include up to three visits and could include remote data collection for certain procedures. Remote data collection will be completed by phone, email, or video conference using a secure Emory-approved platform (e.g., Zoom). Most participants will complete their study visit in three sessions, each lasting around 2.5 hours.

Clinic Procedures

At your study visit, you will be asked to complete the following:

1) Questionnaires and health surveys
2) Cognitive assessments
3) Eye tracking evaluation
4) Vital signs
5) Blood draw
6) Lumbar puncture
7) Cardiovascular assessments
8) Magnetic Resonance Imaging (MRI)

You may also be asked to do the following:

- Complete remote data collection by phone, email, or video conference using a secure Emory-approved platform (e.g., Zoom).
- Be an advocate for the study by participating in video recordings and/or providing testimonials.

Sample Collection & Storage and Other Assessments

Questionnaires and Health Surveys

A study staff member will help you review and update the health history questionnaire you previously completed and may provide other brief surveys. That process will take about 15 minutes.

Cognitive Assessments

Several questionnaires and assessments of your thinking and memory will be administered. The tests may take 75-90 minutes to complete.

Eye Tracking Evaluation

We will ask you to view various images on a computer monitor while it records your eye movements.

Vital Signs

Study staff will collect your height, weight, waist circumference, body temperature, heart rate, and blood pressure. This will take about 10 minutes.

Blood Draw

Up to 10 tablespoons (100mL) of blood will be drawn from a vein in your arm. You will be asked not to eat for at least three (3) hours or drink caffeine for at least two (2) hours before this procedure. On rare occasions, another blood sample may be requested (if the sample is insufficient or if a new scientific question requires a new blood sample). This procedure will take about 10 minutes.

Lumbar Puncture

A lumbar puncture (LP) may be performed as part of this study. If you have a lumbar puncture test, we are asking for permission to use the fluid collected for research. If fluid is collected for the purposes of this study, the procedure will be as follows:

A lumbar puncture is a procedure where fluid that surrounds the brain and spinal cord is removed by inserting a needle in the lower back. You will be asked not to eat for at least three (3) hours or drink caffeine for at least two (2) hours

before this procedure. For this procedure, you will lay on your side curled up in a ball, or sit up and bend forward, depending on your anatomy. The lower part of your back will be cleaned with antiseptic. A provider will inject local anesthetic (lidocaine, 1%) into the skin of your lower back. When the area is numb, a very thin needle will be inserted into the spinal canal in the lower back, well below the level where the spinal cord ends. About 30 milliliters (2 tablespoons) of spinal fluid will be removed for analysis and storage. Your body replaces this spinal fluid within 1-2 hours.

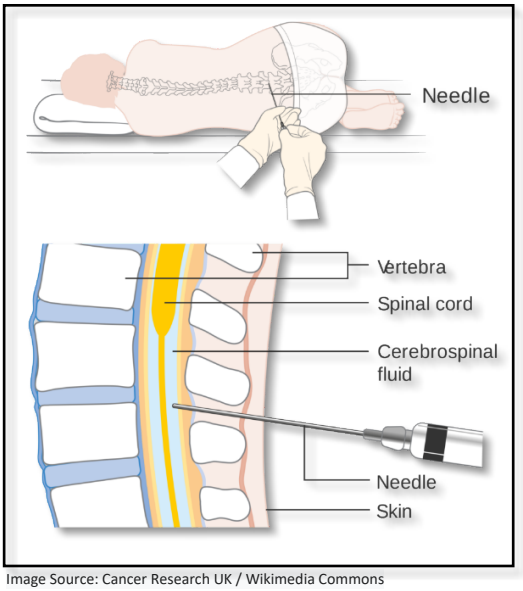

Image Source: Cancer Research UK / Wikimedia Commons

The lumbar puncture will take about 30 minutes, and you will rest for about 20-30 minutes afterward. You should not do any strenuous physical activity for the next 24-48 hours. This includes lifting, bending, doing housework, and gardening, or doing exercise such as jogging or bicycle riding.

Study staff will contact you the day following your lumbar puncture to ask how you are feeling.

Cardiovascular Assessments

Electrocardiogram (ECG): You will also undergo a standard measurement of your heartbeat, which will require us to place several electrodes on your chest, wrist, and ankles.

Carotid Intima-Media Thickness (CIMT): A CIMT scan is a non-invasive test that will be performed easily and quickly while you are lying down. Using a hand-held probe, the technician will scan the carotid arteries in the neck to detect hidden plaque buildup and increased thickness of the artery wall. The entire test is painless, and there is no exposure to dangerous radiation.

The Arterial Pulse Wave Analysis: A test called the “arterial stiffness test” will be done to measure the stiffness of your blood vessels. The arterial stiffness test does not involve injection of any medicines or any cuts to be made in the skin. During this test, you will be asked to lie down on an exam table. You will be asked to keep your arm very still, and a blood pressure cuff is placed on the arm. The cuff is inflated twice: once for a blood pressure read, second for a pulse rate read. Afterwards, a blood pressure cuff is placed on the thigh for a pulse read. The carotid pulse rate will be measured by placing the probe over the carotid artery.

The faster the speed, the stiffer your blood vessels are, possibly as a result of high blood pressure. The test should take about 10 to 15 minutes to complete.

You will be asked not to eat for at least three (3) hours or drink caffeine for at least two (2) hours before the vascular assessments. The vascular assessments will take about 30 minutes.

Magnetic Resonance Imaging (MRI)

You will be asked to complete a brain imaging (MRI) session. The scanner will expose you to strong magnetic fields and radio frequency pulses to create images of your brain. The scanner is a large box with a tube in the middle, in which you will lie while the scan is being done. The tube is about 6 feet long and 25 inches around.

To complete the MRI scan, you will be asked to remove all jewelry and other metal objects. You will enter a large room where the scanner is located and will lie on your back on a narrow table, which will slide into the scanner. Foam padding will be used to keep your head from moving. During the scan, you will hear repetitive tapping and other loud noises. You will be provided ear plugs and/or earmuffs to reduce the noises.

While in the scanner, we will use an eye-tracking camera that takes videos of one of your eyes to measure your eye activities.

During a portion of the scanning process, you will breathe through a disposable mouth-piece air higher in carbon dioxide than normal air (5-8%) for about two minutes, pure oxygen for about two minutes, and normal air for about 6 minutes. This will take up to 10 minutes in total. The normal level of carbon dioxide in a person's lungs is typically about 5-6%, breathing the air higher in carbon dioxide will increase the carbon dioxide concentration in your lungs by about 1-2%.

Pregnancy Test
If you are female and are capable of having children, you will need to give a urine sample for a pregnancy test before completing the imaging portion of the study visit. This procedure will take about five minutes.

Autopsy/Brain Donation
A lot can be learned about the human brain by studying it under a microscope. Therefore, we are asking each person taking part in this study whether they will consider agreeing to brain donation for research (autopsy) at time of death. If you would like to learn more about donating your brain, please let the study staff know.

What are the possible risks and discomforts?

Cognitive Assessments Risks: You may find these assessments to be stressful and frustrating or result in fatigue and boredom.

Eye Tracking Evaluation Risks: There are no risks associated with this procedure.

Vital Sign Risks: There may be some temporary discomfort due to the blood pressure cuff inflation.

Blood Draw Risks: Mild pain and possible bruising and infection as well as possible lightheadedness or fainting may occur.

Lumbar Puncture (LP) Risks: Up to 30 milliliters (about 2 tablespoons) of spinal fluid may be taken during the lumbar puncture. Your body makes about 20 milliliters of spinal fluid every hour and will make up for the loss quickly. Risks related to the procedure are listed below. To minimize these risks, the lumbar puncture procedure will be performed by a clinician specifically trained in the procedure.

Frequent Risks:
- Momentary pain and discomfort in your lower back
- Soreness in your lower back post-procedure

Less Frequent Risks:

- Headache

Rare Risks:

- Allergic reaction to the local anesthetic (lidocaine 1%)
  - This would cause swelling and a rash on your skin where the anesthetic was injected. Please tell us if you have ever had a reaction to local anesthetic before (such as when you were visiting the dentist).
- Low pressure headache
  - Sometimes, a low pressure headache may develop due to leakage of spinal fluid. If this headache persists it may require additional treatment. In rare instances, a blood patch (injection of some of your blood into the lumbar puncture site to patch the spinal fluid leak) may be required. This often relieves the headache immediately.
- Infection, damage to the nerves in your back, and bleeding that may affect the spinal cord or brain.
  - The risk of these is very small.

Cardiovascular Assessment Risks: This set of tests is similar to having your blood pressure taken. There may be some temporary discomfort due to the blood pressure cuff. The ECG stickers may cause some discomfort or a rash on your skin.

Magnetic Resonance Imaging (MRI) Risks: An MRI scan exposes you to strong magnetic fields; however, there is no evidence this is directly harmful to you. Strong magnetic fields are capable of moving metal objects. Therefore, if you have any metal objects or fragments in your body, other than dental work, or you have a cardiac pacemaker, you must let the staff know. The area in which you lie is confining and some people may find that uncomfortable. If you are affected in this way, it will be important for you to let us know, as this could adversely affect the results of the study and would lead us to discontinue your participation.

The MRI scanner produces a loud knocking noise. A very small number of patients have reported a loss of hearing from this noise. You will be given ear plugs to reduce this risk. You may experience a temporary decrease in your hearing abilities accompanied by a ringing in the ears. This should stop within 48 hours from the time you were scanned. If this does not stop within 48 hours, please contact Dr. James Lah, MD at 404-727-3509.

You should stay away from places with loud noises for 24 hours after you have been scanned. If you must be in a loud noise environment, you should use hearing protection. Ear plugs are available to take home, on request.

Breathing in the mask with air rich in CO_2 is well tolerated by most people, including those with neurological diseases, such as history of stroke. This procedure has been performed numerous times in our center without complications. The reported potential side effects may include a feeling of dizziness, faintness, or anxiety during CO_2 inhalation. Patients with chronic obstructive pulmonary disease or severe pulmonary diseases might not tolerate this procedure and will be excluded.

Pregnancy Related Risks: To protect against possible side effects of the imaging procedures, women who are pregnant or nursing a child will not complete the imaging portion of the visit. If you become pregnant, there may be risks to you, the embryo, or fetus. If you are a woman of childbearing ability, you will be asked to take a urine pregnancy test. If you think you may be pregnant, please contact your study coordinator or research personnel. Women who are pregnant or nursing at the time of their visit will be excluded from the imaging procedures.

Other Risks: Other risks may include possible loss of confidentiality by accidental release of confidential information. To help avoid this problem, your samples and results will be labeled with a unique ID number or code. Extensive effort will be made to keep identities confidential. There will be no direct link between your samples and your name. This code will allow researchers to link clinical information about you with your samples without knowing your name.

Unknown Risks: Due to the investigational nature of this study, there may be other risks that are currently unknown. 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.

Who owns my study information and samples?

If you join this study, you are donating your samples and information. You will not receive compensation for your samples or information. If you withdraw from the study, data and samples already collected may still be used for this study. If you withdraw from the study, you will not be able to request destruction of samples already provided. Your records and donated samples may be used for an indefinite period of time.

The analysis of your samples and information may help create new diagnostic tests, medicines or other commercial uses. Emory University will own the testing, samples, and images and will have all rights in the samples and any information, data, discoveries, materials or other products that come from the samples. This includes the right to determine how the test results, samples, and images are used, directed or disposed. You will not receive any compensation for the samples or for data, products, materials, discoveries, or other information that comes from the samples.

Will I benefit directly from the study?

This study is not designed to benefit you directly. However, the information learned may help us better understand the aging process and the diseases that occur while aging. The results may be of future benefit to you or your family as well as patients with these disorders and/or members of their families.

Because participants are often curious about their own information, we are developing means of allowing access to some of the data collected during your visit for your personal interest. This information is not intended for any medical diagnostic or treatment purposes.

Will I be compensated for my time and effort?

You will receive up to a total of $225.00 in gift cards for this visit. If you complete your visit over multiple days, you will receive the gift card when you return to complete all procedures. If you are unable to complete the entire visit, you may receive a reduced amount. If you participate in an additional session to re-collect images that were not of high enough quality to analyze, you will receive an additional $75 (gift card). If you participate in an additional session to re-attempt the lumbar puncture if your first attempt was unsuccessful, you will receive an additional $100 (gift card).

Upon completion of study MRI procedures, a 3D model of your brain will be printed and sent to you.

New/Incidental Findings

In general, we will not give you any individual results from the study of the samples you give us. Research results will not be revealed to you or to your family now or in the future unless it affects your medical care. 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. We do not release research results because it takes a while to discover the meaning of those results. If we become certain

about the meaning of the research results, we will try to make that test available. If the test becomes available, we will make you aware of this test.

Study Partner

Some participants may develop cognitive concerns over the duration of the study. Participant cognitive testing results are reviewed monthly during a meeting with study leadership. If concerns about your cognitive status arise during your participation in the study, we will contact you to discuss results and provide recommendations.

We will also ask you to bring a study partner to future visits. This should be an individual with whom you have a close personal relationship and could be present for your study visits. The study partner will be asked to participate in the consenting process and complete various questionnaires. They will be there to ensure that all procedures are understood, and that consent is obtained freely and voluntarily. They are not required to be present for the remainder of the study visit.

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

Emory will keep all research records private to the fullest extent allowable 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 study results.

Certificate of Confidentiality

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

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

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

- Giving state public health officials information about certain infectious diseases,
- Giving law officials information about abuse of a child, elderly person, or disabled person.
- Giving out information to prevent harm to you or others.
- Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

Storing and Sharing your Information

Your samples, genomic data and health information will be stored and shared with other researchers at Emory and collaborating institutions, including commercial entities. All information collected will be captured electronically and entered into a secure computer database. 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.

Researchers at Emory are interested in learning about social determinants of health. Social determinants of health are environmental conditions that can impact an individual's overall health. To learn about this area of science, we may need to collect your residential history (i.e., your previous addresses) using external sources. This information can be

used with national data sources about things such as education quality, healthcare access, air pollution exposure, and other factors as a way of estimating positive and negative environmental exposures during your life. We may need to validate your residential history with you.

Genetic Information

Your samples will be stored for future studies, including genetic testing. The DNA (genetic material) and plasma in your blood sample will be isolated and stored for these studies. Permanent cells may be created. Once DNA is isolated, it can be duplicated indefinitely for future research. A code is used to link your samples to all the records collected and used for this study. This includes but not limited to your clinical information, answers to any questionnaires, cognitive tests and any additional records you release. All samples are stored at Emory or a secure, Emory-approved storage facility. Some of your genetic and health information may be placed in large research databases. Information that could directly identify you will not be included.

For example, the National Institutes of Health (NIH) national research database has compiled data from more than 100,000 people, and the Emory Brain Study may place information in this database. Research using information in an NIH database or other large research databases will be reviewed and approved by an ethics committee whose duty it is to protect the privacy of your information.

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.

Medical Record

If you have been an Emory patient before, then you already have an Emory medical record. If you have never been an Emory patient, you do not have one. An Emory medical record will be made for you if an Emory Atlanta 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 medical record you have now or any time during the study.

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

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

In Case of Injury

If you get ill or injured from this research, contact the person listed in the contact section of this form. Emory will help you get immediate medical care. However, Emory and the Federal Government (including but not limited to the National Institutes of Health as applicable) do not have programs to pay for this medical care or compensate you if you are hurt from being in this study.

The costs for any treatment or hospital care you receive as the result of a study-related injury that are not covered by a health insurer will be billed to you.

You do not give up any legal rights you may have by being in this study, including any right to pursue a claim through the legal system.

Costs

There will be no cost to you for participating in this study. The study can provide transportation to your study visit. Please let your recruiter know if you need transportation arranged for you. You will not be charged for any of the research activities. If the study procedures result in any medical complications that would not fall under "injury" as discussed above, the cost of treatment for those complications may be charged to you or your insurance.

If you are seen as a patient for clinical care at one of the study sites, your clinic or hospital visit is not part of the research protocol. You are responsible for payment for your clinic/hospital visits and for any tests or procedures that your doctor orders as part of your clinical care.

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 Emory Healthy Aging Study (in which you already participate), the Emory Healthy Brain Study (this 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 cognitive, movement, and other assessments you have before and during the study.
- Results of data obtained through your participation in the Emory Healthy Aging Study.
- 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 this study, and of future studies that are covered by this consent and authorization. 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 elderly or disabled adults.

Authorization to Use PHI is Required to Participate:
By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form 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. 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.
    - Other researchers and centers that are a part of this study.
    - Government agencies that regulate the research including the Office for Human Research Protections.
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.

- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your PHI may be shared with that new institution and their oversight offices. PHI will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

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 you may revoke (take back) your permission to use your information. If you want to do this, you must contact the study team at:

Dr. James Lah
c/o Kate Sanders
Emory University
6 Executive Park Drive NE, Floor 2, Room 265
Atlanta, GA 30329

A revocation letter will be provided with this consent form for your convenience.
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
If you have questions about the study procedures, appointments, research-related injuries, or other questions or concerns about the research or your part in it, contact Najé Simama (Project Manager) at 404-727-6472, Kate Sanders (Director, Projects) at 404-727-6174, or Dr. James J. Lah (Principal Investigator) at 404-727-3509.

This study has been reviewed by an ethics committee to ensure the protection of research participants. If you have questions about your **rights as a research participant**, or if you have **complaints** about the research or an issue you would

rather discuss with someone outside the research team, contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu.

To tell the IRB about your experience as a research participant, fill out the Research Participant Survey at **https://tinyurl.com/ycewgkke**.

Consent and Authorization

Please print your name and sign below if you agree to be in this study. Your signature below shows that you agree with the following:

- Researchers can use information gathered during my clinical and research evaluations for research purposes. They may put my information in their research database and store my samples in its bio-bank.
- I agree to the collection and use of my samples and data for research purposes.
- I agree to allow my samples and evaluation data to be stored for future testing, including DNA (genetic) tests and cell line duplication.
- I agree that the researchers may contact me to update the research records or to ask me about participating in new research projects.

TO BE FILLED OUT BY SUBJECT ONLY

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