

## **Informed Consent**

**Study Title:** Emory Healthy Aging Study  
**Principal Investigator:** James J. Lah, MD, PhD, Department of Neurology  
**Funding Source:** The Goizueta Foundation

Thank you for your interest in our 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. It is entirely your choice. Even if you decide to take part, you can change your mind and withdraw at any time.

If you have further questions after reading the following information, please contact us before consenting to the study.

### **What is the purpose of the Emory Healthy Aging Study?**

The goal of the Study is to find factors that increase the likelihood of retaining good health as one ages. Aging directly affects brain health, heart health, the immune system, and many other aspects of our overall health. This study will establish a large database of health information from a diverse group of people who may be followed for five years or as long as the study continues to prove useful. We hope to include up to 100,000 participants in this study.

A second goal is to identify people who might be eligible to participate in related, but separate, research studies.

Our long-term goal is to find ways to prevent and treat diseases that occur more often as we age.

### **Who is eligible?**

Individuals over the age of 18 are eligible for this study.

### **Why is this study important to researchers?**

Scientific advances over recent years have led to big changes in the treatment of many diseases. Despite these advances, we still do not understand why some people develop diseases such as Alzheimer's disease, and others do not. We also do not have any effective treatments for many conditions that may develop as we age.

Scientists are just beginning to find tests and markers that may help predict if a person will develop a particular disease. By understanding these markers, we may be able to find new ways to prevent the development of the disease. We hope this study will teach us more about the aging process, and help to develop new ways to prevent and treat various conditions that may arise as we age.

### **How much time does this study take? How long is it?**

Your participation in the study may take 30-90 minutes or less every 3-12 months. The maximum time burden will not exceed 6 hours per year. We will continue the study for at least five years and continue afterwards for as many years as it is useful.

**How do I participate in this study?**

If you agree to take part in this project, you should read this information completely and electronically agree in the section provided at the end of this consent.

**What data will be collected?**

If you agree to participate, we will collect the following information:

1. Your demographic and contact information.
2. The health history of you and your biological parents and siblings.
3. Responses to study surveys and other assessments.
4. Electronic medical record information (if you have received treatment from an Emory physician or Emory-affiliated physician).

All data collected as part of this study will be used for research purposes and not for clinical care.

**What are the risks of participating and how will you protect my privacy?**

Your privacy is very important to us. 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.

Emory will keep any research records we create private to the fullest extent allowable by law. We will comply with legal requests and orders such as subpoenas or court orders.

Even with the tightest security, there remains a potential risk to confidentiality. To decrease this risk, all of the information you provide will be maintained in a secure database with access limited to individuals directly involved in the research. The Emory Healthy Aging Study is deeply committed to issues of privacy, and will continue to take every available measure to ensure the security of your personal information.

Another potential risk is the surveys or questionnaires may cause frustration, anxiety or boredom, with the time it takes to complete them. You may skip any question you do not wish to answer.

**Is there compensation or a benefit from this study?**

You will not receive any payment or other financial benefit by being in this study. This study is designed to learn more about preventing and treating age-related medical conditions, you may not experience any direct benefit.

Some indirect benefits to participation may include:

- The opportunity to participate in a clinical trial or research study that may help you predict, prevent, or treat certain health conditions.

- The opportunity to help doctors and others in the future prevent and treat age-related medical conditions.

**Are there other options to this research?**

This study does not provide treatment or medical interventions. Your other option is to decline to participate.

**Will this be in my medical record?**

Your study information will not be in your Emory medical record unless you share the information with your Emory Healthcare provider.

**Can I withdraw from the study?**

Yes, you have the right to leave the study at any time without penalty.

**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 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 study includes:

- Medical information about you including your medical history and present/past medications.
- Survey, questionnaire and assessment results.
- Demographic and contact information.

**Purposes for Which Your PHI Will be Used/Disclosed:**

We will use and share your PHI for the conduct and oversight of this database, and of future studies that are covered by this consent and authorization. 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, 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.

**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.
- Emory may use and disclose your PHI 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 Goizueta Foundation is funding this study. They may use and disclose your PHI to make sure the research is done correctly. They may also disclose your PHI to other people and groups 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. These include the Emory IRB, the Emory Research and Healthcare Compliance Offices.

**Expiration of Your Authorization**

Your PHI will be used until this research study ends.

**Do I have to participate in the Study?**

Your participation in this study is voluntary. If you change your mind about the study, you have the right to revoke (take back) your permission. Simply fill out the revocation form online to withdraw your active participation or email the study team at [HealthyAging.Decline@emory.edu](mailto:HealthyAging.Decline@emory.edu).

At that point, the researchers would not collect any more of your PHI. However, they may use or disclose the information you already gave them.

**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 the Privacy Rules will not protect your information. 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. The Goizueta Foundation, and people and companies working with them on this study are not covered by the Privacy Rules. They will only use and disclose your information as described in this Consent and Authorization.

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.

**Who should I contact if I have questions?**

If you have any questions regarding the Emory Healthy Aging Study or if you need to tell us about a change in your data, please email us at [HealthyAging@emory.edu](mailto:HealthyAging@emory.edu).

If you have questions about this study, your part in it or if you have concerns or complaints about the research you may contact the following:

James J. Lah, MD, PhD, Study PI: 404-727-3509; email: [jlah@emory.edu](mailto:jlah@emory.edu)

Richard Kuerston, Program Director: 404-712-7314; email: [rkuerst@emory.edu](mailto:rkuerst@emory.edu)

If you have questions about your rights as a research participant or if you have concerns or complaints about the research, please contact the following:

Emory Institutional Review Board: 404-712-0720; toll-free: 877-503-9797; email: [irb@emory.edu](mailto:irb@emory.edu)

**Consent for Voluntary Participation:**

By clicking agree to this consent form, you acknowledge that you understand the information presented above as well as the nature of the study. You are not giving up any legal rights. A copy will be sent to your email address after acceptance.

**What does consent include?**

This voluntary consent gives the study permission to:

1. Store the data you provide
2. Contact you for clarification or further information about data that you provide
3. Contact you periodically (approximately every 3-12 months) to request that you update your profile and to complete additional online assessments or surveys
4. Share your information with other researchers for research purposes
5. Access any medical records that Emory may have for you
6. Contact you about future clinical trials and related research that may be suitable for you