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: Answer ALS: Individualized Initiative for ALS Discovery

Principal Investigator: Jonathan D. Glass, MD

Sponsor: Packard Center for ALS Research at Johns Hopkins and ALS Finding a Cure

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

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

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

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This web site will not include information that can identify you. At most the web site will include a summary of the results. You may search this web site at any time.

We are asking you to take part in this study because you have been diagnosed with having Amyotrophic Lateral Sclerosis (ALS).

Approximately 1,000 individuals with ALS will participate in this multicenter study at 6 sites across the USA. Approximately 200 individuals with ALS will participate at the Emory ALS Center.
What is the purpose of this study?
This research is being done to create a large repository of cells called induced pluripotent stem cells (iPSC), bio-fluid samples (blood and spinal fluid (optional)), and cell lines for ALS gene identification. This will be combined carefully with collected measures of the pattern of the symptoms people with ALS have and how these change over time.

We may use the cells taken from your blood to create a type of cell known as a pluripotent cell. This type of cell can be used to create different types of tissue, including brain cells. Your cells might be used in research involving genetic alteration of the cells.

Lastly, there is an optional lumbar puncture to obtain cerebrospinal fluid (CSF). CSF will be stored in a repository, which is a place where items can be stored.

All samples will be labeled with a code. This code will not include any personal information about you.

This study is being done for research purposes only. The results of your genetic testing will not be given to you or your study doctor. This includes any information from results that we obtain now or in the future. The results will never go into your medical records.

We do not expect that any information important to your personal health will be learned from this research and you will not be given results from research testing of your samples. It is possible that we may share the information acquired from this study with other scientists. No identifiable information will be released to any such outside agency without your permission.

During research on the samples that you provide, it is possible that what we learn or create will be shared with other academic, non-profit and for-profit entities. This includes hospitals, universities and businesses. These materials might be used for further research and development of tools, therapies and treatments including cell therapies. The research may lead to new products, research tools, or inventions that may be patented. This may in turn lead to commercially available therapies and treatments for which financial profit may be received and kept by hospitals, universities and businesses. It is possible that the people who make the discoveries will profit. By agreeing to participate in this research and by signing this form, you are agreeing to give up any possible or potential financial interest you may have in the samples you are donating and the information obtained from them. You will not be able to share in the profits from the use or sale of products developed from your participation in this study.

By signing this consent form, you agree to give blood and CSF (optional) samples for this study as stated above.

There are three parts of this study:
• The first part involves screening (making sure you can take part in the study).
- The second part is collecting blood samples that will be used to create induced pluripotent stem cells (iPSC), analyze genes that may be related to ALS, and identify factors in the blood. This may help us understand how to diagnose ALS and learn more about how the disease progresses. Some participants may elect to have a lumbar puncture (spinal tap) to collect cerebrospinal fluid (CSF), which will be used for research purposes.
- The third part is to examine participants every 3 months to evaluate how their condition changes over a one year period. This involves several test measures of overall function, strength, breathing function, and memory.

**Part One: Screening and Enrollment:**
1) There will be a screening interview to see whether or not you meet the requirements for the study. If you do meet the study entry criteria, your participation will begin. We may begin the collection of fluids and assessments at this time or make an appointment for you to return.

**Part Two: Collection of Blood and Fluid Samples**
1) We will use the cells taken from your blood to create a type of cell known as a pluripotent cell. This type of cell can be used to create different types of tissue, including brain cells. Your cells might be used in research involving genetic changes of the cells.
2) Some of your blood will be sent for genetic testing, including whole genome sequencing. This will help us understand whether ALS participants carry genes which could cause ALS or put them at risk for ALS. We will study parts of your blood, such as DNA, that will help us to understand what happens when genes function abnormally and how it might be related to disease. DNA (deoxyribonucleic acid) is the building block of an individual’s genetic make-up. We hope that DNA testing will help us diagnose and develop new treatments for ALS and other diseases. The New York Genome Center (NYGC) will receive approximately ½ tablespoon of your blood sample for sequencing and analysis. The other ½ tablespoon of your coded blood sample will be stored at the NEALS Biorepository.

We will draw a total of about 236 ml (approximately 16 tablespoons) of blood during the entire course of the research study.

Lumbar puncture (spinal tap): We will take cerebrospinal fluid (CSF) samples at any visit that you elect. This sample can be collected anywhere from 0 to 5 times during the study. Since this is an optional portion of the study, you do not have to have any CSF fluid collected should you choose.

CSF is the fluid that cushions the spinal cord and brain. Lumbar puncture is a clinical test to obtain a small amount (about one to two tablespoons) for analysis. More details of the lumbar puncture are provided below. These tests are being done to determine what factors may be present in people with ALS that can help us understand the disease. The remaining CSF will be stored in a repository for future research projects. If after signing the consent form, you do not
wish to have your CSF drawn via a lumbar puncture, you may withdraw your consent to have this performed at any time.

Depending on your decision to have CSF samples taken, we could collect anywhere from about 30 ml (about 2 tablespoons) to 150 ml (about 10 tablespoons) of CSF during the whole course of the research study.

Part Three: Long-Term Evaluation of ALS participants

Participants in this study will come to Emory for study visits every 3 months for one year. They will undergo the following measurements:

1) ALS Functional Rating Scale-revised (ALSFRS-r): This questionnaire consists of 12 questions about your ability to function in certain daily activities. This questionnaire will take about 5-10 minutes to answer.
2) ALS Cognitive Behavioral Scale (ALS-CBS): This is a short measure of thinking and behavior in patients with ALS. The cognitive section includes 8 tasks, with a possible total score of 20. The behavioral section (ALS Caregiver Behavioral Questionnaire) is made up of questions sensitive to changes in the brain. It has a set of questions that compare changes in personality and behavior since the onset of ALS, as well as yes/no questions about mood, laughing/crying, and fatigue. It is completed by a caregiver, family member or other informant during the same time that the patient completes the assessment. The questionnaire usually takes about 2 minutes to complete.
3) Slow Vital Capacity (SVC) Testing: The SVC measures the maximum amount of air you can exhale following a deep breath. For this test, you will be asked to hold a mouthpiece in your mouth, breathe in deeply, then blow out as long and hard as you can. The test will be done with you seated in a chair and then repeated while you are lying on the exam table. This test will take about 15-20 minutes.
4) Strength testing (Hand Held Dynamometry [HHD] and Grip Strength): You will have muscle strength testing performed on your upper and lower limbs. For this procedure, the evaluator will hold a small device (called a hand-held dynamometer) in their hand and will push against your arms and legs while you try to hold against this pushing. Additionally, you will be asked to squeeze a grip testing device. This testing will take about 15 minutes.
5) Ashworth Spasticity Scale: You will have your limbs moved quickly to see if they are stiff.

For what type of research will my samples be used?

Your samples and information will be used mainly to study ALS and other motor neuron diseases. Your samples and information may also be used for research on other conditions as comparisons to other diseases. This could include a wide variety of conditions such as mental illness, HIV/AIDS, cancer, reproduction and others.

- We may perform different types of biological and genetic research with your sample. Genetic research may include looking at some or all of your genes and DNA to see if there are links to your health condition or to other conditions.
• We may create a “cell line” from your sample that will allow researchers to have an unlimited supply of your cells for research.

• We will use your cells to create pluripotent stem cells. This type of cell can be used to create different types of tissue, for example, heart, muscle, or lung cells. Your cells might be used in research that alters genes in the cells in order to study different diseases and normal healthy processes. Your cells might be mixed with other human cells, animal cells, or grown in lab animals like mice.

• We may share your samples and any cell lines that are created, your DNA, genetic information, your health information, and results from research with other central tissue or data banks, so that researchers from around the world can use them to study many conditions.

In order to allow researchers to share research results, agencies such as the National Institutes of Health (NIH) have developed secure banks that collect and store research samples and/or data from genetic studies. These central banks may store samples and results from research done using the NEALS Biorepository samples and health information. The central banks may share these samples or information with other qualified and approved researchers to do more studies. Results or samples given to the central banks will not contain information that directly identifies you. There are many safeguards in place at these banks to protect your privacy.

**How long will my samples and information be kept?**
There is no scheduled date on which your samples and information in the bank will be destroyed. Your samples may be stored for research until they are used, damaged, decayed or otherwise unfit for analysis. The code linking your samples to your medical record may be kept indefinitely so that your samples and updated health information may be used for research in the future.

**Will I get results of research done using my samples?**
No. The research we are doing is only a stepping-stone to understanding ALS. Therefore, information from this research will not be returned to you. Any significant information discovered using your samples would be published in medical journals.

**Request to collect and store biospecimens for future research**
As part of this research study, we are asking you to let us store your biospecimens and health information for future research. This research could include other diseases.

**What should you know about the cell lines that will be derived in the course of this study?**
• The cell lines created will be similar or identical to you genetically.
• The cell lines may be kept indefinitely.
• There is the possibility that your cells or the created cell lines might be used in research that will involve genetic manipulation of the cells or the mixing of human and non-human cells in animal models.
• The cell lines may be shared with researchers both inside and outside of Emory, including our commercial partners.
• The cell lines may be used to develop treatments for a variety of diseases and conditions.
• Gene sequencing of your DNA provides researchers with the code of your genetic material.

The study doctor can provide you with additional information if you have questions. Also, further information about our use of your biospecimens can be found in this consent document under the heading ‘What happens to Data and Biospecimens that are collected in the study?’

Who owns my study information and samples?

Emory University and our research partners work to understand and cure diseases. The biospecimens and/or data you provide are important to this effort. If you join this study, you should understand that you will not own your biospecimens or data, and should researchers use them to create a new product or idea, you will not benefit financially.

With appropriate protections for privacy, Emory may share your biospecimens and information with our research sponsors and partners.

Your participation is completely voluntary and you have the right to refuse to be in this study. You can also choose to stop participating at any time after giving your consent. Withdrawing from the study only affects uses and sharing of information after the study doctor gets your request. However, at anytime, you have the right to withdraw permission for your samples and information to be stored in the NEALS Biorepository.

If you withdraw permission, your samples and your information will be destroyed. However, it will not be possible to destroy samples and information that have already been provided to researchers for analysis or been analyzed by researchers.

Study Information Included in Your Electronic Medical Record

A notation that you are taking part in this research study may be made in your electronic medical record. Information from the research that relates to your general medical care may be included in the record (for example, list of allergies, results of standard blood tests done at the hospital labs).
If you agree to be in this study, we will ask you to do the following things:

**Screening, Informed Consent, and Baseline (Visit 1)**
The screening visit may take up to four hours.

During this visit, we will do some tests and procedures to see if you qualify to take part in this research study. The study doctor will review the results of these tests and procedures. If you don’t qualify, the study doctor will tell you why.

**During this visit, the following tests and procedures will be performed:**
- Obtain written informed consent before you complete anything
- Review inclusion and exclusion criteria for the study
- Review past and current medical history. This includes your demographic information, ALS diagnosis history, and any medications you are currently taking including vitamins and nutritional or herbal supplements
- Measure vital signs including height and weight
- Collect blood samples for DNA, pluripotent stem cells, plasma, and serum. About 4-5 tablespoons of blood will be collected
- Complete a lumbar puncture to collect cerebrospinal fluid (optional)
- The following assessments will be completed:
  - Complete ALSFRS-R questionnaire
  - Complete ALS Cognitive Behavioral Scale
  - Complete ALS Caregiver Behavioral Questionnaire
  - Complete lung function testing (SVC)
  - Perform Ashworth Spasticity Scale
  - Perform hand held dynamometry (HHD) and grip strength testing

**Visits 2, 3, 4, and 5**

This visit may take about 1 - 2 hours.

After the screening visit (Visit 1), you will return to Emory every 3 months where the following assessments and procedures will take place:
- Review any changes to your health
- Review any medications that you are taking
- Assess any adverse events related to research participation that may have occurred
- If your blood was not collected at the screening visit for DNA, it will be collected once at either visit 2, 3, 4 or 5. About 1 tablespoon of blood may be collected
• Collect blood samples for plasma and serum. About 2-3 tablespoons of blood will be collected.
• Complete a lumbar puncture to collect cerebrospinal fluid (optional)
• The following assessments will be completed:
  o Complete ALSFRS-R questionnaire
  o Complete ALS Cognitive Behavioral Scale
  o Complete ALS Caregiver Behavioral Questionnaire
  o Complete lung function testing (SVC)
  o Perform Ashworth Spasticity Scale
  o Perform hand held dynamometry (HHD) and grip strength testing

If you are unable to attend the in person visit at Emory for visits 2, 3, 4, or 5, a study staff member may contact you by telephone to make the following assessments:
• Assess any adverse events that may have occurred related to research participation
• Review and document concomitant medications, including nutritional supplements
• Administer ALSFRS-R
• Record Key Study Events. The information that may be recorded includes feeding tube placement, tracheostomy, diaphragm pacing system implantation, and general notes on disease progression

**Post-Participation Follow up Period**
We will call or email you approximately every 3 months after your last study visit (Visit 5). During these calls/emails, we will ask about your health and perform the ALS Functional Rating Scale (ALSFRS-R). We may also collect this information from your past clinical visits unrelated to this research study. The information that may be recorded includes the ALSFRS-R, vital capacity measurements, feeding tube placement, tracheostomy, diaphragm pacing system implantation, and general notes on disease progression.

By signing this consent form, you agree to have your medical chart reviewed and the data used for this study as stated above.

**Volunteer Responsibilities**
As a volunteer in this study, you have certain responsibilities to help ensure your safety. Please follow these important responsibilities listed below:
• Keep all scheduled appointments. All study visits and tests will take place at Emory.
• Report all medical problems to the study staff.
• If you decide to stop taking part in the study, you must inform the study doctor or staff.

**How long will I be in the study?**
If you choose to take part in this study there will be a total of 5 visits. However, if you decide to have the lumbar puncture(s), you could have up to 10 visits at Emory. You will be in this study for the rest of your life or until you decide you no longer want to participate, or until the study ends.
The study visits will occur at The Emory Clinic, building B, suite 2000.

**What are the possible risks and discomforts?**
There may be side effects from procedures that are not known at this time.
The most common risks and discomforts expected in this study are:

**Blood Draw**
A blood draw may cause pain, bruising and/or bleeding at the puncture site. Occasionally, a person feels faint when blood is drawn. Rarely, an infection may develop, which can be treated.

**Lumbar Puncture**
Lumbar puncture is a standard procedure used in medical practice. When spinal fluid is removed during a lumbar puncture, the risks include headache, bleeding and pain at the site where the needle was put in, and infection. Pain during the lumbar puncture procedure will be prevented or minimized by using local anesthesia (lidocaine). Infection after a lumbar puncture is very rare, but serious, and would be treated with antibiotics.

About 1 out of 3 people who have a lumbar puncture develop a post-lumbar puncture headache. Headache can occur if the lining around the spinal fluid (dura) is torn and some of the fluid leaks out. Post-lumbar headaches are more common in females and in people less than 30 years old. This headache can be mild to severe. You may also have nausea, dizziness and ringing in the ears.

If you develop a headache, you will need to lie down to reduce the headache pain and symptoms. Post-lumbar puncture headaches get worse when you are sitting or standing. Occasionally, the headache may be severe enough to interfere with your normal daily activities, such as going to work or school. If this happens, there are no plans to pay you for time missed from work or school or for other costs, such as paying for a babysitter.

If you get a headache, you should contact Dr. Glass, who is in charge of this study. Pain medication will be given to you, if needed. If the headache lasts more than three days, a procedure called a blood patch may be performed. This procedure involves taking blood from your arm and injecting it in the same place where the spinal needle was put in during the lumbar puncture. The clotting of the blood in this space should stop further fluid leaking and stop the headache.

**Study Testing**
Slow Vital Capacity (SVC): The risks and discomforts associated with the Slow Vital Capacity testing include feeling tired, light-headed or short of breath. These symptoms will disappear with rest.
Questionnaires: The ALSFRS-R and Frontotemporal Dementia Screening Assessment (ALSCBS). Questionnaires may cause you to feel sad or upset about how ALS has changed how well you can perform daily activities, and how it has affected your quality of life. You may get tired or bored when we are asking you questions or you are completing questionnaires. You do not have to answer any question you do not want to answer.

**Privacy Risks**
There may be risks to your privacy and the privacy of your relatives from storing your information in the repository. Although the NIH takes measures to protect privacy, we do not know how likely it is that your identity could become re-connected with your genetic and health information.

If your genetic information were re-identified, personal information about you, your health and your risk of disease could become known to others. This could present unknown risks. Current federal law will help protect you from genetic discrimination in health insurance and employment.

**DNA Risks**
Genetic information that results from this study does not have medical or treatment importance at this time. However, there is a risk that information about taking part in a genetic study may influence insurance companies and/or employers regarding your health, or have a negative impact on family or other relationships. We will not place information about the study or the results of the study in your medical record. Your samples will be coded.

Genetic information is unique to you, even without your name or other identifiers. For this reason, genetic information like DNA may be used to identify you and possibly your family members. The main risk of allowing us to store and use your samples and certain limited health information for research is a potential loss of privacy. We will protect your privacy by labeling your samples and information only with a code, and keeping the key to the code in a password-protected database. However, there is still the risk of loss of privacy as new ways of tracing genetic information are being developed that may make re-identification of genetic information possible.

**Other Risks**
Reviewing health-related information might be stressful or make you feel uncomfortable. You do not have to answer any questions you do not want to, and you may stop the interview at any time if it is too uncomfortable.

Information that could be used to identify you will only be shared with researchers within Emory who have approval of the Emory Institutional Review Board (IRB). Information that likely could be used to identify you will not be shared with researchers outside Emory.

There may be side effects and discomforts that are not yet known.
It is possible that the researchers will learn something new during the study about the risks of participation. 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.

**Will I benefit directly from the study?**
This study is not designed to benefit you directly. Your condition may even get worse. This study is designed to learn more about ALS. The study results may be used to help others in the future.

**Will I be compensated for my time and effort?**
You will not be paid for being in this study.

**What are my other options?**
You do not have to participate in this study to receive care for your disease. There may be other clinical research studies available to patients with ALS. The study doctor can discuss with you other studies open for enrollment at this time. Riluzole (Rilutek®) is the only drug approved for the treatment of ALS. Taking riluzole or not taking it does not affect your eligibility to be in this study. Whether or not you choose to participate in a clinical trial will not affect your care at Emory.

**How will you protect my private information that you collect in this study?**
Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

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

**Storing and Sharing your Information**
Data from this study will be stored in a data repository at the Massachusetts General Hospital (MGH) Neurological Clinical Research Institute (NCRI). The purpose of this data repository is to capture and store data for neurological clinical research. The repository will combine data from multiple studies. We will share combined datasets with researchers who want to advance understanding of neurological disease. Your data will be used to study illnesses and conditions affecting, or related to, the brain and nerves.

For this research project, some identifiable information may be collected and stored in the database. This might include information like your date of birth or the date your symptoms began. At the end of this project, all data will be coded (all identifying information including dates will be removed). The coded dataset combined with information from other projects will then become available for sharing with other researchers.
We do not think that there will be further risks to your privacy by sharing your samples and/or whole genome information with other researchers; however, we cannot predict how genetic information could be used in the future.

DNA may be stored, used in other genetic studies, or for any other type of DNA analysis (known or currently undiscovered) that is applicable to understanding or targeting disease, especially ALS. The information from these genetic studies may be made available to collaborators for medical research in academic, not-for-profit, or commercial institutions. Results of DNA testing from this study will not go into your medical record.

The NYGC will also be conducting the sequencing of the coded samples and doing the analysis of the sequencing. These genetic and coded clinical data may be shared with collaborators of this study as well as uploaded to scientific databases, such as the NIH Database of Genotypes and Phenotypes (dbGaP).

**Global Unique Identifier (GUID)**
As part of your participation in the study, a unique subject number will be assigned to you that will allow researchers to see if you have been involved in more than one research study or database for patients with ALS. If you have participated in more than one study or database, this unique subject number will help connect information across studies. This subject number will also allow your de-identified data to be combined with data from other research studies to increase the likelihood of meaningful analysis. Only this subject number and not your personal identifiable information will be accessible to other investigators. This unique subject number may make it possible for a study doctor who used this unique subject number in another study that you took part in to identify you.

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

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

Be aware that GINA does **not** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance, and does not apply to employers with less than 15 employees.
In addition to GINA, the State of Georgia has laws that prohibit insurers from using genetic testing information for any non-treatment purpose. However, like GINA, this state law protection has exclusions: life insurance policies, disability income policies, accidental death or dismemberment policies, Medicare supplement policies, long-term care insurance policies, credit insurance policies, specified disease policies, hospital indemnity policies, blanket accident and sickness policies, franchise policies issued on an insurance policy written as a part of workers’ compensation equivalent coverage, or other similar limited accident and sickness policies.

**Privilege**

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

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

As part of this study, we will collect information about your health and your individual genes. This information will be sent to a 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.

**Are there benefits to sharing your genetic information?**

There is no direct benefit to you from placing your genetic information in the repository. Allowing researchers to study your genetic information may lead to a better understanding of how genes affect health. This may help other people in the future.
**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:
- Genetic testing
- Other testing performed in research labs for investigational purposes

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 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 Dr. Glass at telephone number 404-778-5000. You should also let any health care provider who treats you know that you are in a research study.

**Costs**
There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities.
Withdrawal from the Study
You have the right to leave a study at any time without penalty.

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.

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 date of birth, 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 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. 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
- The U.S. Office of Human Research Protections in the U.S. Department of Health and Human Services – the government agency that oversees patient safety issues in human research for studies conducted in the U.S.
- Coordination Center and Data Management staff at the Massachusetts General Hospital Neurological Clinical Research Institute (NCRI), Boston, MA - the academic group responsible for managing the study and for all aspects of data collection and processing
- Representatives of New York Genome Center (NYGC) – individuals receiving your coded blood samples for DNA analysis
- Representatives of Cedars-Sinai Regenerative Medicine Institute – individuals receiving your coded blood for cell line generation
- Representatives of the Northeast ALS Consortium (NEALS) Biorepository – individuals receiving your coded blood and CSF samples for banking
- The Institutional Review Board of Emory – committees that make certain that your rights are protected
- The Steering Committee for the study - the group responsible for reviewing coded safety data for the study and for making decisions about the progress of the study
- The Packard Center for ALS Research at Johns Hopkins and the ALS Finding a Cure Foundation - the sponsors of the research study
- 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.

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. The Sponsor, and people and companies working with the Sponsor 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.

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.

Expiration of Your Authorization
Your PHI will be used until this research study ends.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact the study team at 404-778-3807 or Dr. Jonathan Glass
101 Woodruff Circle, Suite 6000
Atlanta GA 30322

At any time you may choose not to participate in the lumbar puncture procedure. You may still participate in the main study even if you do not choose to participate in the lumbar puncture.

_______ Yes, I would like to participate in the lumbar puncture. (please initial response)
_______ No, I would not like to participate in the lumbar puncture. (please initial response)

Will you allow us to store the biospecimens we collect for this study for future research?

_______ Yes, my biospecimens may be stored for future research. (please initial response)
_______ No, I do not give permission for my biospecimens to be stored for future research. (please initial response)
Contact Information
Contact Dr. Glass at: 404-778-3807 (404-778-5000 after hours)
- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury
- 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

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