[Medical] Research Informed Consent
Title of Study: Analysis of Human ALS Tissue

Principal Investigator (PI): Jeffrey Loeb, M.D., Ph.D.
421 E. Canfield, 3122 Elliman
Detroit, MI 48201
313-577-9827

Funding Source: Departmental

Purpose

You are being asked to be in a research study to find out what goes wrong in the nervous system and muscles in people with ALS (amyotrophic lateral sclerosis) and other disorders of the neuromuscular system. While many research studies in animals have given us important clues, they have not yet provided a sufficient understanding to produce effective treatments. This study is therefore being conducted entirely with human tissues that will be removed from your body shortly after you die. This study is being conducted at Wayne State University and the Detroit Medical Center. The estimated number of participants to be enrolled at Wayne State University is 10 per year. **Please read this form and ask any questions you may have before agreeing to be in the study.**

In this research study, after you die, fresh tissues will be removed from various regions of your nervous system and muscles. These will be stored and then used for a variety of research studies into the cause and development of cures for ALS.

Study Procedures

If you agree to take part in this research study, you will be asked to donate fresh tissue from various regions of your nervous system and muscles. As the proteins and genes in your body degrade over time, a major focus here will be to remove your tissues as quickly as possible after you die. To maximize the quality of the tissue, if you agree to participate in this study, you will be referred to a hospice nearby our medical center. We will coordinate with the hospice to transport your body to our pathology suite for rapid tissue removal and processing within one hour after you expire. It is important that you discuss this with your family members in advance. Once your body arrives to the pathology suite, a full autopsy will be performed as well as sampling of nervous and neuromuscular tissues that will be stored and used in our research programs to understand and treat your disorder. Your family will be provided with a full autopsy report as part of the usual autopsy procedure.

Benefits

As a participant in this research study, there will be no direct benefit for you; however, information from this study may benefit other people now or in the future.

Risks

By taking part in this study, you will experience no additional risks from removing tissues from your body after you die.
By discussing your death, you may experience unwanted feelings. You may also find the discussion of an autopsy to be disturbing.
There may be risks involved in taking part in this study which are not known to researchers at this time.

Alternatives

The only alternative is to not participate in the study.

Study Costs

Participation in this study will be of no cost to you.

Compensation

You will not be paid for taking part in this study.

Research Involving the Future Use of Biological Specimens

Samples from your body will be used for our research studies and the remainder will be stored frozen for future studies. As medicine is rapidly advancing, we do not know all of the possible studies that will be done, but we will not link the sample to your name or any information that would allow anyone to identify you. The sample will be housed in a research laboratory at Wayne State University and can be destroyed at any time. It is also possible that your sample will be provided to a third-party to conduct specialized testing based on formal arrangements between Wayne State University and the third party. In this event, we would not provide any of your personal information that would enable the third party to reveal your identity.

Confidentiality

All information collected about you during the course of this study will be kept confidential to the extent permitted by law. You will be identified in the research records by a code name or number. Information that identifies you personally will not be released without your written permission. However, the study sponsor, the Institutional Review Board (IRB) at Wayne State University, or federal agencies with appropriate regulatory oversight [e.g., Food and Drug Administration (FDA), Office for Human Research Protections (OHRP), Office of Civil Rights (OCR), etc.) may review your records.

When the results of this research are published or discussed in conferences, no information will be included that would reveal your identity.

Voluntary Participation/Withdrawal

Taking part in this study is voluntary. You have the right to choose not to take part in this study. You are free to withdraw from participation in this study at any time prior to your death. Your decisions will not change any present or future relationship with Wayne State University or its affiliates, or other services you are entitled to receive.

If after your death, your family chooses not to have your body undergo an autopsy for tissue removal, than your participation in the study would be withdrawn.

Questions

If you have any questions about this study now or in the future, you may contact Dr. Jeffrey Loeb or one of his research team members at the following phone number 313-577-1689. If you have questions or concerns about your rights as a research participant, the Chair of the Institutional Review Board can be contacted at (313) 577-1628. If you are unable to contact the research staff, or if you want to talk to someone other than the research staff, you may also call (313) 577-1628 to ask questions or voice concerns or complaints.

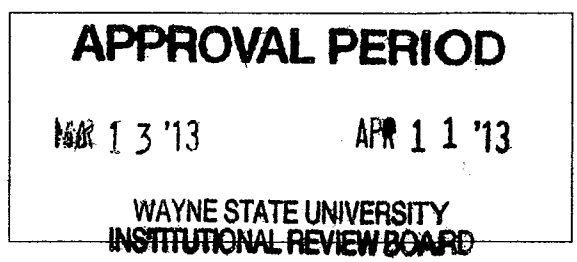
Consent to Participate in a Research Study

To voluntarily agree to take part in this study, you must sign on the line below. If you choose to take part in this study you may withdraw at any time. You are not giving up any of your legal rights by signing this form. Your signature below indicates that you have read, or had read to you, this entire consent form, including the risks and benefits, and have had all of your questions answered. You will be given a copy of this consent form.

Signature of participant / Legally authorized representative*	Date
Printed name of participant / Legally authorized representative *	Time
Signature of witness**	Date
Printed of witness**	Time
Signature of person obtaining consent	Date
Printed name of person obtaining consent	Time

*Remove LAR reference if you don't intend to consent participants that have or may have LAR.

**Use when participant has had this consent form read to them (i.e., illiterate, legally blind, translated into foreign language).



Signature of translator	Date
Printed name of translator	Time

HIPAA Authorization

A federal regulation, known as the "Health Insurance Portability and Accountability Act (HIPAA)" gives you certain rights concerning the use and disclosure (sharing with others) of your Protected Health Information (PHI). This regulation provides safeguards for the privacy and security of your information. Your permission (authorization) is required for the use and sharing of any protected health information collected as part of this research study. If you are not willing to sign this authorization to use and/or disclose your PHI by the research team, you will not be eligible to take part in this research study.

The principal investigator (PI) and his research team will use your medical records and information created or collected as part of this research study. Your PHI is important for the PI and his research team in order to collect information about you during the study, to be able to contact you if needed, and to provide treatments to you during the study, if required. The PI may send out your study related health information to the sponsor or other entities involved in this study.

Your medical records, which may contain information that directly identifies you, may be reviewed by representatives from groups identified below. The purpose of these reviews is to assure the study is being conducted properly, that data is being obtained correctly or for other uses authorized by law. These reviews occur at the study site or in the PI's research office and can take place anytime during the study or after the study has ended.

The PHI that will be "USED" for this research includes the following: name, elements of dates, medical record number, and any unique identifying numbers or characteristics of code.

The PHI that will be "DISCLOSED" or shared with others for this research includes the following: elements of dates and any unique identifying numbers or characteristics or code.

Your study information may be **used** or **shared** with the following people or groups:

- The PI, co-investigators, and key personnel of WSU and the Detroit Medical Center associated with the research project
- WSU's Institutional Review Boards (IRB)
- Authorized members of WSU and Detroit Medical Center's workforce who may need to access your information in the performance of their duties.
- Federal agencies with appropriate regulatory oversight (e.g., FDA, OHRP, OCR, etc.) may review your records

Once your information has been released according to this Authorization, it could be released again and may no longer be protected by the HIPAA regulations.

This Authorization does not expire. The research team may need to correct it or provide missing information about you even after the study has ended, and your medical records may be needed to assist in this process.

- During your participation in this study you will have access to your medical record and any study information that is part of that record. The PI is not required to release research information that is not part of your medical record.

You may withdraw (take back) your permission for the **use** and **disclosure** of your PHI for this research at anytime, by **writing** to the PI at the address on the first page of this form. Even if you withdraw your permission, the PI for the research project may still use your PHI that was collected prior to your written request if that information is necessary to the study. If you withdraw your permission for use of your PHI, you will also be withdrawn from the research project. Withdrawing your authorization **will not** affect the health care that will be provided by the Detroit Medical Center and/or the WSU School of Medicine Practice Plans.

Authorization to use and disclose PHI

- By signing this document, you are authorizing the PI to **use** and **disclose** PHI collected about you for the research purposes as described above.

_____ _____

Signature of participant Date

_____

Printed name of participant

- For participants unable to give Authorization, the following individual is acting on behalf of the research participant (e.g., children, mentally impaired, etc.).

_____ _____

Signature of authorized representative Date

_____ _____

Printed name of authorized representative Relationship to the participant

_____ _____

Signature of person obtaining Authorization Date

_____ _____

Printed name of person obtaining Authorization Time

APPROVED

MAR 13 2013

WAYNE STATE UNIVERSITY
INSTITUTIONAL REVIEW BOARD